Supreme Court, U.S.
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No. 01-1333

In The

Supreme Court of the United States

CAROL JEAN BROOKS,

Petitioner,

v.

HOWMEDICA, INC., a Delaware corporation and a division of Pfizer Hospital Products Group; PFIZER, INC.; and HOWMEDICA INTERNATIONAL, LTD.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Eighth Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Petitioner was injured by a medical device that had been approved for marketing by the Food and Drug Administration ("FDA"). She sought compensation from respondents for their failure to adequately warn her according to state common law. In *Medtronic* v. *Lohr*, 518 U.S. 470 (1996), this Court held that such claims are not expressly preempted by the Medical Device Amendments of 1976. See 21 U.S.C. §360k(a). However, the Court was divided on certain points and the case did not explicitly address tort immunity for products with pre-market approval from the FDA. Since then, state and federal courts have reached conflicting conclusions about the propriety and scope of express preemption under such circumstances. In this case the Eighth Circuit, sitting en banc, held that respondents are entitled to summary judgment on the basis of express federal preemption under §360k(a). The question presented is:

> Whether state tort claims for failure to adequately warn of product hazards are expressly preempted by 21 U.S.C. §360k(a) when the product receives pre-market approval and ongoing regulatory oversight from the FDA.

PARTIES TO THE PROCEEDINGS

Petitioner is Carol Jean Brooks.

Respondents are Howmedica, Inc., a Delaware corporation and a division of Pfizer Hospital Products Group; Pfizer, Inc.; and Howmedica International, Ltd.

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Carol Jean Brooks respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eighth Circuit in this case.

OPINIONS BELOW

The en banc opinion of the court of appeals is reported at 273 F.3d 785 and is reproduced in the appendix to this petition at 1a. The panel opinion of the court of appeals is reported at 236 F.3d 956 and is reproduced at 43a. The opinion of the district court is not reported and is reproduced at 68a.

JURISDICTION

The en banc judgment of the court of appeals was entered on December 11, 2001. The jurisdiction of this Court is invoked under 28 U.S.C. §1254(1).

STATUTES AND REGULATIONS INVOLVED

Section 360k(a) of Title 21 of the United States Code provides:

> "State and local requirements respecting devices
>
> "(a) General rule. Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –

"(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

"(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."

Section 808.1(d) of Title 21 of the Code of Federal Regulations provides in part:

"State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act [21 U.S.C. §360k(a)] because they are not 'requirements applicable to a device' within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

"(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code

(warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices."

FACTS AND PROCEDURAL HISTORY

1. Petitioner's injury and state law claim. Petitioner worked for 30 years as a nurse before her career ended in 1995 as a result of occupational asthma. 2a-3a; Appendix to Petitioner's Brief at 431, *Brooks* v. *Howmedica, Inc.*, 236 F.3d 956 (CA8 2001) (No. 00-1188) ("A."). Before she contracted the disease, petitioner's job duties included mixing a bone cement product that was manufactured, sold, and distributed by respondents for surgical uses. Unfortunately, the mixing process produces harmful chemical vapors, including methyl methacrylate. 2a-4a. Petitioner alleges that her repeated and increasing exposure to these vapors between approximately 1983 and 1992 caused her occupational asthma. *Ibid.*; A.9-11, 412-20, 437. She also alleges that a causal relationship between methyl methacrylate and asthma was established in 1985, and that respondents failed to adequately warn her of the risks associated with their product. 3a-4a, 25a; A.78, 460-65 and n.4, 468-72.

In March 1997, petitioner filed this state common law failure-to-warn claim in the United States District Court for the District of Minnesota. Jurisdiction was premised on 28 U.S.C. §1332. A.9-12. Respondents later moved for summary judgment arguing, in relevant part, that petitioner's lawsuit was expressly preempted by 21 U.S.C. §360k(a). 4a, 10a; A.47. This express preemption defense was supported, respondents contended, by the FDA's 1971 decision to permit the

product to be marketed and by FDA regulation since then.

2. Federal regulation of medical devices. By 1938 Congress had prohibited the manufacture or interstate shipment of adulterated or misbranded drugs and medical devices, and required FDA approval of new drugs before they entered the market. See generally *Medtronic* v. *Lohr*, 518 U.S. 470, 475 (1996); 21 U.S.C. §355. Over the next several decades, medical devices became both more important to human health and far more dangerous. As injuries mounted, Congress responded with the Medical Device Amendments of 1976 ("MDA"). See *Lohr*, 518 U.S., at 475-76. Among other provisions, the MDA expanded the definition of "medical device," 21 U.S.C. §321(h); 42 Fed. Reg. 63,427, 63,427 (1977), and categorized every such product into one of three classes. The classes are based on risk to human health, with class III including the most dangerous devices. See *Lohr*, 518 U.S., at 476-78.

Extending the concept of FDA approval from the new-drug context, Congress also added a Pre-Market Approval ("PMA") process for most class III medical devices. *Ibid.* (noting exceptions); 21 U.S.C. §360e(a). To market such devices a manufacturer must assemble a range of product information, including safety studies and proposed product labeling. 21 U.S.C. §360e(c)(1). The manufacturer's submission is then reviewed by FDA to determine whether the applicant has provided a "reasonable assurance" that the proposed device is safe and effective. *Id.*, §360e(d)(2)(A)-(B). Once approved, generally applicable FDA regulations impose some limits on product alteration. Thus, certain product changes must be pre-

approved by FDA, 21 CFR §814.39, and where FDA "specified" a condition for approval, the manufacturer may not produce or market the device "in a manner that is inconsistent with" the specified condition, *id.*, §814.80. In many cases, FDA issues a form letter notifying the applicant of the agency's decision to approve the product for marketing and reminding the applicant of generic record-keeping and reporting obligations. See A.146-55.

FDA approval does not entail specific or enduring government dictates about device design, manufacturing, or labeling. Product attributes initially and ultimately depend upon choices by applicants, on whose data FDA largely depends. See 21 CFR §§814.20, 814.44. And a variety of proposals might satisfy the general criteria for pre-market approval. See 21 U.S.C. §360e(d)(2); 21 CFR §§814.45, 860.7. Nor does federal law prohibit product improvement. Manufacturers are ordinarily free to enhance consumer knowledge about product risks – even by changing product labeling. FDA must be notified of and will subsequently review such changes, but federal regulations permit "Labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction," or that "add or strengthen an instruction that is intended to enhance the safe use of the device." 21 CFR §814.39(d)(2)(i)-(ii). Such changes can be made as soon as FDA is notified, and they may remain in effect unless and until FDA says otherwise. *Id.*, §814.39(d)(1); see *Lohr*, 518 U.S., at 497 n.16.

Finally, the MDA provided neither a private cause of action for consumers, nor FDA authority to compensate individuals injured by medical devices. Cf. 21

U.S.C. §360h(b), (e) (granting FDA authority to order repairs, replacements, refunds, and recalls). The FDA may attempt to *prevent* injuries, but its function does not include compensating consumers in damages for personal injuries that actually occur.

3. The regulatory record in this case. Respondents' product entered the market as a "new drug" after completing the New Drug Application ("NDA") process in 1971, but since 1976 it has been regulated as a "medical device" with PMA. 6a-7a; 21 U.S.C. §360j(l)(1), (3)(A); 21 CFR §888.3027; A.127-28, 146, 338. The NDA and PMA processes are comparable and equally "rigorous." See 4a-5a, 71a; *Lohr*, 518 U.S., at 477-78; 21 U.S.C. §§355, 360e; A.338.

Respondents were regulated by FDA during and after the product's approval process, an injury occurred despite FDA's preventative efforts, and respondents had an opportunity to reduce the risk. Respondents did not propose, and FDA did not consider, changing the product labels or package insert to specifically warn health-care professionals that preparing the product can cause occupational asthma, and to instruct them on how to avoid that danger. In contrast, other warnings for this product specify hazards and precautions, and new warnings have been added since the product was first approved for marketing – some proposed by FDA, others by respondents:

a. FDA-prompted labeling. Before FDA approval in 1971, the agency drafted language for the package insert, which respondents then incorporated into their application:

> "As the liquid monomer is highly volatile and flammable, the operative room should be provided with adequate air circulation. Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated vapors of the monomer which may produce irritation of the respiratory tract, eyes, and possibly the liver." 5a-6a; see A.118-19, 158, 163, 176.

This warning did not refer to asthma, it was not included on the package label, and the reference to air circulation was linked to volatility and flammability.

In 1975, the FDA conducted a review of methyl methacrylate vapor inhalation and operating-room personnel. 8a; A.125. Also in that year, the FDA asked respondents to revise their package insert regarding volatility and flammability, and respondents agreed to the following language: "As the liquid monomer is highly volatile and flammable, the operating room should be provided with adequate ventilation so as to eliminate the maximum amount of monomer vapor." 8a; A.119, 126. In addition, as a condition of FDA approval for expanded use of their product, respondents agreed to send a "Dear Doctor" letter. See 9a; A.127, 315-30. The letter directed the reader's attention to certain inhalation studies and the product's package insert, and suggested a review of hospital facilities for adequate ventilation and discontinuance of exposure for sensitive individuals. See 9a (noting risks of dermatitis and "other allergenic responses"); A.325-26. Respondents sent the letter in 1976 to orthopaedic surgeons, operating-room supervisors, and hospital administrators. See 9a.

b. Manufacturer-initiated labeling changes. Two years after pre-market approval, respondents proposed an additional warning for the package insert to address the risks of contact dermatitis. See 8a. After redrafting respondents' proposal to specify the risk and proper precautions, FDA approved the new warning. See 8a; A.123-24, 226. In 1986 respondents again proposed and the FDA approved a new warning, this time for contact-lens users. Respondents had discovered that soft contact lenses could be damaged by exposure to bone-cement vapors. See 10a; A.128.

4. The MDA's preemption provision. The 1976 legislation added 21 U.S.C. §360k(a). That provision disables certain state and local requirements "with respect to a device" if they are also "different from, or in addition to, any requirement applicable under this chapter to the device." The statute does not refer to state common law, and there is no evidence that Congress specifically considered or intended preemption of state tort. See *Lohr*, 518 U.S., at 487-91 (plurality opinion); *Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367, 1378-81 (CA11 1999).[1] By regulation, FDA has endorsed a narrow interpretation of §360k(a) and the preemptive scope of its own requirements. See 21 CFR §808.1(d); *Lohr*, 518 U.S., at 498 n.18.

In *Lohr*, this Court attempted to explain the meaning of §360k(a). There, a plaintiff sought damages under state tort law to compensate her for injuries

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[1] It appears that medical device manufacturers themselves did not begin to assert §360k(a) against products liability claims until more than a decade after the provision became law. See *Goodlin*, 167 F.3d, at 1381; Margaret J. Porter, The *Lohr* Decision: FDA Perspective and Position, 52 Food & Drug L.J. 7, 8 (1997).

caused by an allegedly defective class III pacemaker lead. The FDA had approved the product for marketing under its "substantial equivalence" process, and had promulgated applicable labeling and manufacturing regulations. 518 U.S., at 477-80, 497-98. But the majority held that none of the plaintiff's claims – including a failure-to-warn claim – were preempted.

The Court splintered at certain points, but some conclusions were unanimous. First, not every state law damages claim is preempted by §360k(a). *Id.*, at 491 (plurality opinion); *id.*, at 503, 508 (Breyer, J., concurring in part and concurring in judgment); *id.*, at 513 (O'Connor, J., concurring in part and dissenting in part). Second, there is no preemption when a tort claim is premised on state duties "equal to, or substantially identical to, requirements" imposed by federal law. *Id.*, at 494-97 (majority opinion); *id.*, at 513 (O'Connor, J., concurring in part and dissenting in part). And third, there can be no preemption when the FDA has not issued regulations both applicable to the device and related to the field of manufacturer conduct at issue in the tort suit. Hence the plaintiff's design-defect claim was not preempted because the FDA had not issued any design specifications for the device in question. *Id.*, at 492-94 (majority opinion); *id.*, at 513-14 (O'Connor, J., concurring in part and dissenting in part) (arguing that federal labeling and manufacturing regulations preempted warning and manufacturing claims, yet not the design-defect claim).

But a serious debate emerged over whether §360k(a) could preempt a tort claim that does *not* parallel an existing federal requirement. By a 5-4 margin, the Court held that the plaintiff's failure-to-warn claim was not preempted, even if it would do more

than incidentally enforce a federal labeling requirement. The Court scrutinized the text of §360k(a) and the FDA's preemption regulation, and identified the

> "overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest. . . . . The statute and regulations, therefore, require a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations." *Id.*, at 500.

The Court then held that the plaintiff's failure-to-warn claim survived, for two independent reasons. First, although FDA's labeling regulations applied to the device, their generality deprived them of preemptive force. They "reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements." *Id.*, at 501. Second and similarly, the plaintiff's failure-to-warn claim was premised on a "general duty" applicable to all manufacturers alike, not requirements " 'with respect to' specific devices such as pacemakers." *Id.*, at 501-02 (quoting §360k(a)). Any state requirements were thus ineligible for preemption: "they are not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements." *Id.*, at 501.

Although he joined the majority opinion discussed above, Justice Breyer also filed a concurring opinion. He agreed that the failure-to-warn claim was not pre-empted, *id.*, at 508, that courts can rely on FDA's preemption regulation for guidance, *id.*, at 505-07, and that "specific" federal requirements are necessary for preemption, *id.*, at 507. In addition, Justice Breyer echoed the majority's concern that eligible state and federal requirements must be compared for some degree of interference or conflict between them. See *id.*, at 505-08. But in his view §360k(a)'s reference to state law "requirements" could extend to state law damages claims. *Id.*, at 503-05.[2] He therefore did not join the plurality portions of Justice Stevens' opinion because he was not convinced that MDA preemption of damages claims would be "rare." *Id.*, at 508; cf. *id.*, at 489-90 (plurality opinion) (suggesting that "requirements" refers to statutes and agency regulation, not the application of common law by judge and jury).

5. The decisions below. The district court granted respondents' motion for summary judgment on the sole basis of express federal preemption. 86a. Although the court recognized conflicting authority from other jurisdictions, 81a-84a, it followed a pre-*Lohr* Eighth Circuit case involving a medical device with PMA. See 84a-86a (discussing *Martello* v. *Ciba Vision Corp.*, 42 F.3d 1164 (CA8 1994), *cert. denied*, 515 U.S. 1161 (1995), and a non-MDA case).

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[2] To illustrate, Justice Breyer posed a hypothetical in which a manufacturer could not possibly comply with both an FDA regulation dictating a specific product attribute (a 2-inch wire), and a contrary design entailed by a plaintiff's theory of liability at trial. *Id.*, at 504.

A panel of the Eighth Circuit reversed, with one judge dissenting. 64a. Attempting to apply *Lohr*, the majority searched for specific state requirements that would conflict with specific federal requirements. 50a-52a. The panel was willing to conclude that specific state requirements would be generated by the application of general state tort principles, 52a-54a, and the panel believed that specific federal requirements had been imposed by the FDA during and after pre-market approval, 54a-57a. But the majority could find no conflict between these asserted requirements: "FDA regulations do not in fact mandate that [the product's] labeling and package inserts remain frozen in their 1971-approved state"; rather, respondents are "free to provide more information, and more detailed warnings, to consumers." 58a-59a (citing 21 CFR §814.39(d)(2)(i)-(ii)).

The full Eighth Circuit granted respondents' petition for rehearing en banc, vacated the panel's opinion, and affirmed the district court's grant of summary judgment. 2a. The en banc court indicated that it agreed with the panel that §360k(a) preemption demands that "specific" state requirements "conflict" or "interfere" with "specific" federal requirements. 18a-19a, 27a. The majority nevertheless concluded that preemption was appropriate, relying on "rigorous" premarket review by FDA, 20a, coupled with post-approval regulation in the field of inhalation toxicity:

> "The FDA was deeply involved in drafting and editing the warnings on the [product] label and package label, beginning with the product's approval in 1971 and continuing on through the period in which [petitioner] was exposed to it. Through its approval of the

> PMA application for [the product] and its continuing series of directives, the agency imposed specific federal requirements on [respondents]. The failure to warn claim [petitioner] seeks to assert could impose state requirements which conflict or interfere with these federal directives." 27a.

The dissenters endorsed the majority's purported analytical framework, but they disagreed that there was any conflict between state and federal requirements. 30a. The dissent stressed that FDA regulations permit device manufacturers to enhance warnings, see 21 CFR §814.39(d); that any federal concerns about new warnings can be vindicated through that process; but that respondents did not invoke it:

> "[Respondents] could have altered [their] label or package insert – unilaterally – to alert users to the dangers of contracting asthma, pending permanent FDA approval of those warnings. [¶] Had the FDA refused permission to add asthma warnings, [petitioner's] failure-to-warn claim would almost certainly be preempted. . . . . That hypothetical example is not the present case, however." 32a-33a.

The majority did not dispute this characterization. Cf. 23a (majority opinion) (observing that *after* a warning-enhancement application "has been approved, modified, or denied, the manufacturer must comply with the FDA's decision").

ARGUMENT

The question presented is an important and recurring issue of federal law that divides the state and

federal courts. The arguments for and against preemption have largely played themselves out. Equally significant, the divergent approaches to §360k(a) can be traced back to the various interpretations offered by the Members of this Court in *Lohr*. Neither Congress nor the FDA has acted to eliminate the confusion, and so this Court is the proper place to end the debate. The writ should therefore be granted to repair the fracture in *Lohr*, to settle the disagreement among state and federal courts that it engendered, and to confirm that manufacturers are not immune from liability when they violate generally applicable state duties to warn about product risks – at least absent square conflict with specific FDA dictates.

1. The question presented is important to nationwide public and private interests. Aside from the contradictory results reached by state and federal judiciaries, this Court has already confirmed the significance of §360k(a) to human health and state interests. While *Lohr* considered a medical device that lacked PMA, devices subject to PMA are both the most important and the most dangerous to consumers. Moreover, pro-preemption decisions undervalue state law. The traditional concern of the States for consumer health and safety triggers a stout presumption against federal preemption. To override the States' choices about how best to protect and compensate product users, Congress and the FDA must speak clearly. *Lohr*, 518 U.S., at 485; *Hillsborough County* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 717-18 (1985).

In addition, the scope of §360k(a) is a matter of pressing concern for plaintiffs and defendants alike. FDA has no statutory authority to compensate the injured. This means that countless consumers will be

left without compensation if the express preemption provision is construed as broadly as some courts and medical device manufacturers would have it. Conversely, countless manufacturers will pay arguably preempted judgments in those jurisdictions where state tort law is preserved – unless a final answer is provided by this Court.

Obvious federal interests are at stake as well. The Federal Government itself rejected the pro-preemption stance of courts like the one below in a post-*Lohr* *amicus* brief to this Court.[3] That position is in line with the FDA's preemption regulation and congressional intent. The Members of Congress who enacted the MDA in 1976 to *add* consumer protection could not have fathomed that they were *eliminating* products liability claims for the most dangerous category of medical devices, absent palpable conflict with FDA dictates.

2. State and federal courts are deeply divided over the scope of §360k(a) preemption. Uncertainty about consumers' ability to obtain compensation is illustrated by the festering division of authority among state and federal courts. In fact, in more than one State a plaintiff may walk into a county courthouse with a valid tort claim and freely sue for injuries caused by a

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[3] Brief for United States as *Amicus Curiae* at 14-18, *Smith Indus. Med. Sys., Inc.* v. *Kernats*, No. 96-1405 (filed Dec. 1997) (petition stage) ("U.S. Br. in *Kernats*"). Although the FDA withdrew a proposed clarifying regulation for procedural reasons, 63 Fed. Reg. 39,789 (1998), the agency's preemption regulation remains in force and the Federal Government has not altered its position, see Brief for United States as *Amicus Curiae* at 5 n.2, *Buckman Co.* v. *Plaintiffs' Legal Comm.*, No. 98-1768 (filed June 2000) (petition stage); see also *Auer* v. *Robbins*, 519 U.S. 452, 462 (1997) (the Federal Government's *amicus* position may warrant deference).

medical device with PMA; but litigating the same matter across the street in federal court will result in a prompt dismissal based on §360k(a) preemption.[4] The situation has become intolerable, and it is not getting any better by itself. See *Webster* v. *Pacesetter, Inc.*, 171 F. Supp. 2d 1 (D.D.C. 2001) (most recent published decision; denying preemption).

a. Whether any state requirements are subject to preemption. Respondents' preemption defense would be resolved differently in several other jurisdictions, albeit for more than one reason. In some courts petitioner's suit would have survived summary judgment because of the character of the alleged state requirements. As *Lohr* instructed, "[s]tate requirements must be 'with respect to' medical devices." 518 U.S., at 500. A preemption defense should therefore fail here because "the general state common-law requirements in this suit were not specifically developed 'with

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[4] Compare *Weiland* v. *Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149 (Ill. 1999), *Niehoff* v. *Surgidev*, 950 S.W.2d 816 (Ky. 1997) (involving an investigational device), *cert. denied*, 523 U.S. 1005 (1998), *Walker* v. *Johnson & Johnson Vision Prods., Inc.*, 552 N.W.2d 679 (Mich. Ct. App. 1996), and *Connelly* v. *Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996) (en banc) (involving an investigational device; relying on absence of conflict between requirements), *cert. dismissed*, 520 U.S. 1260 (1997), with *Mitchell* v. *Collagen Corp.*, 126 F.3d 902 (CA7 1997), *cert. denied*, 523 U.S. 1020 (1998), *Kemp* v. *Medtronic, Inc.*, 231 F.3d 216 (CA6 2000), *cert. denied*, ___ U.S. ___, 122 S.Ct. 48 (2001), and 20a-27a. California's own appellate courts are divided, see *Steele* v. *Collagen Corp.*, 63 Cal. Rptr. 2d 879 (Cal. Ct. App. 1997); *Armstrong* v. *Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763 (Cal. Ct. App. 1996), *review denied* (Cal. Feb. 19, 1997), while the Ninth Circuit retains an anti-preemption holding, see *Kennedy* v. *Collagen Corp.*, 67 F.3d 1453 (CA9 1995), *cert. denied*, 518 U.S. 1033 (1996), *overruled in part by Papike* v. *Tambrands Inc.*, 107 F.3d 737, 740-42 (CA9), *cert. denied*, 522 U.S. 862 (1997).

respect to' medical devices." *Id.*, at 501. The FDA's preemption regulation is to the same effect. 21 CFR §808.1(d)(1).

Several courts heed this position and reject all (or nearly all) preemption of state tort under §360k(a). For example, in *Oja* v. *Howmedica, Inc.*, 111 F.3d 782 (CA10 1997), one of the respondents in this case was sued for failing to adequately warn about problems with a hip-replacement device. Before the plaintiff's injury the device received PMA and, in response to an FDA investigation, respondent sent out a "Dear Doctor" letter. *Id.*, at 787. The letter identified a product hazard that later occurred in the plaintiff's implant, and it was sent only after FDA had scrutinized information about the problem without demanding additional warnings. See *id.*, at 785, 787, 789. The Tenth Circuit was also willing to agree that respondent was subject to at least one specific, FDA-mandated "requirement" within the meaning of §360k(a). *Id.*, at 789 (identifying a restriction on off-label promotion and assuming that the letter qualified as a preemptive requirement). None of the regulatory history mattered. Like the situation in *Lohr*, "the general state common law requirements imposed by Oja's negligent failure to warn claim were not specifically developed 'with respect to' medical devices. Instead, Oja's negligent failure to warn claim is predicated upon a general duty applicable to every manufacturer . . . . " *Ibid.* (citation omitted). Respondents' preemption defense in this case would meet the same result in the Tenth Circuit and elsewhere.[5]

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[5] See *Armstrong*, 57 Cal. Rptr. 2d, at 771-73 and n.12; *Kernats* v. *Smith Indus. Med. Sys.*, 669 N.E.2d 1300, 1308-09 (Ill. App. Ct.), *appeal*

The court below distinguished *Oja* on the ground that the device there did not have PMA. 21a-22a. But that assertion is (a) inaccurate[6] and (b) irrelevant to the Tenth Circuit's rationale. To be sure, the Eighth Circuit's conclusion prevails in other courts, which appear to reason that state tort suits will always produce sufficiently specific requirements at trial, or (what is much the same thing) that specific federal requirements are sufficient for preemption.[7] Whatever their logic, these rulings contradict cases like *Oja*.

On the merits, the pro-preemption decisions do not square with the majority opinion in *Lohr* and FDA policy. They must rely on a broad reading of Justice

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denied, 675 N.E.2d 634 (Ill. 1996), *cert. denied*, 522 U.S. 1044 (1998), *overruled on other grounds by Weiland*, 721 N.E.2d, at 1153; *Mears* v. *Marshall*, 944 P.2d 984, 987, 993-95 (Or. Ct. App. 1997), *review denied*, 961 P.2d 217 (Or. 1998); *Wutzke* v. *Schwaegler*, 940 P.2d 1386, 1391-92 (Wash. Ct. App. 1997), *review denied*, 953 P.2d 96 (Wash. 1998); see also *Niehoff*, 950 S.W.2d, at 822; *Walker*, 552 N.W.2d, at 686; *Baird* v. *American Med. Optics*, 693 A.2d 904, 909-11 (N.J. Super. Ct. App. Div.) (involving an investigational device), *modified and remanded*, 713 A.2d 1019, 1028-30 (N.J. 1997) (dicta).

[6] The device in *Oja* received PMA after the plaintiff was implanted, but before she suffered symptoms of injury. FDA reclassified the device into class II before trial, but (similar to this case) after the manufacturer began to breach its post-sale common law duty to warn and the plaintiff began to experience pain. 111 F.3d, at 785, 787, 789.

[7] See, *e.g.*, *Martin* v. *Medtronic, Inc.*, 254 F.3d 573, 581-83 (CA5 2001) (reaffirming the circuit's pre-*Lohr* rule that "common law tort claims challenging the safety or effectiveness of a device create specific requirements under state law"), *cert. denied*, ___ U.S. ___, 122 S.Ct. 807 (2002); *Papike*, 107 F.3d, at 740-42 (involving a device- and disease-specific federal labeling regulation); *Fry* v. *Allergan Med. Optics*, 695 A.2d 511, 517 (R.I.), *cert. denied*, 522 U.S. 952 (1997); accord *Mitchell*, 126 F.3d, at 912; *Steele*, 63 Cal. Rptr. 2d, at 885-87; *Worthy* v. *Collagen Corp.*, 967 S.W.2d 360, 371, 376-77 (Tex.), *cert. denied*, 524 U.S. 954 (1998).

Breyer's concurrence. Granted, Justice Breyer agreed with the dissent that §360k(a) *can* preempt state tort claims. *Lohr*, 518 U.S., at 503-05. But that observation was not necessary to his conclusion that the plaintiff's claim survived, and he did not declare that state tort claims impose specific requirements per se. Rather, Justice Breyer indicated that courts should evaluate a plaintiff's specific theory of recovery at trial and its incompatibility with specific federal requirements. See *id.*, at 504-08. If followed, that approach suggests that preemption rests on a specific judicial decree or a jury-endorsed theory of recovery commanding a particular design modification prohibited by federal law. On that theory and at this stage, summary judgment against petitioner is inappropriate. See U.S. Br. in *Kernats* at 17-18 (state courts may refine the common law to avoid conflict with federal law).

But of course the more important point is that too many courts "have struggled mightily," *Kemp* v. *Medtronic, Inc.*, 231 F.3d 216, 224 (CA6 2000), *cert. denied*, ___ U.S. ___, 122 S.Ct. 48 (2001), in attempting to follow *Lohr* and its perceived "ambiguities," *Mitchell* v. *Collagen Corp.*, 126 F.3d 902, 910 (CA7 1997), *cert. denied*, 523 U.S. 1020 (1998). They have reached different conclusions, and their divergent approaches have an outcome-determinative effect in a case like this.

b. Whether any federal requirements have preemptive force. *Lohr* also held that federal law is not preemptive unless a "specific" federal "requirement" applicable to the device can be identified. 518 U.S., at 497-501; *id.*, at 506-07 (Breyer, J., concurring in part and concurring in judgment). But *Lohr* did not formally resolve whether obtaining PMA – which may

entail FDA scrutiny of manufacturer-submitted information, some limits on product alteration thereafter, and ongoing oversight – creates preemptive federal requirements. Several courts hold that it does not.[8] Others disagree.[9]

The latter decisions are incorrect. Standing alone, FDA approval reflects the agency's considered but non-preemptive judgment that the applicant's proposal satisfied generally applicable and minimum federal standards to permit marketing. 21 U.S.C. §360e(d)(2); 21 CFR §814.45. FDA's permission to market neither sets immutable FDA policy with respect to the device, nor converts general standards into specific requirements. *E.g.*, *Goodlin*, 167 F.3d, at 1374-77; *Webster*, 171 F. Supp. 2d, at 9-11. As the Solicitor General explained,

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[8] See *Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367, 1375-77 and n.16 (CA11 1999) (rejecting the Seventh Circuit's holding and concluding that PMA does not impose ascertainable substantive requirements); *Webster* v. *Pacesetter, Inc.*, 171 F. Supp. 2d 1, 2-3, 7-9 (D.D.C. 2001) (same); *Haidak* v. *Collagen Corp.*, 67 F. Supp. 2d 21, 23-24 (D. Mass. 1999); *Weiland*, 721 N.E.2d, at 1152-54 and n.1; *Walker*, 552 N.W.2d, at 682-85; *Sowell* v. *Bausch & Lomb, Inc.*, 656 N.Y.S.2d 16, 20 (N.Y. App. Div. 1997); see also *Kennedy*, 67 F.3d, at 1458-60 (pre-*Lohr*).

[9] See *Martin*, 254 F.3d, at 580 and n.5, 583-85 (noting the split, following pre-*Lohr* Fifth Circuit precedent, and preempting state tort claims that relate to "areas covered in the PMA process," like product labeling); *Kemp*, 231 F.3d, at 226-28 (asserting that PMA converts manufacturer-submitted product information into preemptive federal requirements); *Mitchell*, 126 F.3d, at 911; *Fry*, 695 A.2d, at 516; see also *Steele*, 63 Cal. Rptr. 2d, at 887-88; *Green* v. *Dolsky*, 685 A.2d 110, 117 (Pa. 1996), *cert. denied*, 520 U.S. 1168 (1997); *Worthy*, 967 S.W.2d, at 369, 376.

> "[T]he FDA's grant of a PMA signifies that the FDA has examined the manufacturer's application and determined that the device satisfies the federal criteria for marketing. . . . . As in the case of the premarket notification, labeling, and manufacturing requirements in [*Lohr*], those general criteria establish minimum standards that do not displace state law standards of care or common law duties respecting the medical device." U.S. Br. in *Kernats* at 15.

Consistent with this understanding, labeling decisions are not set in stone. FDA regulations provide a procedure for warning enhancements after initial approval, a procedure that permits manufacturers to warn the public even before FDA consideration of that warning. 21 CFR §814.39(d)(2)(i)-(ii). This promotes timely and updated information about product hazards after a device hits the market, while preserving FDA regulatory authority on a case-by-case basis. Pro-preemption courts give insufficient attention to what the FDA has actually required and prohibited; and they overlook or underestimate the ability of manufacturers to implement product improvements.[10]

Hence, the decision below is both highly questionable and in conflict with other cases to the extent that

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[10] *E.g.*, 23a-27a and n.11 (equating FDA inquiry and response regarding respiratory "irritation" with permanently debilitating occupational asthma, and then reaching outside the record to dispute the state of scientific knowledge); *Mitchell*, 126 F.3d, at 913-14; *Worthy*, 967 S.W.2d, at 376-77 (relying on FDA *findings* about "safety," instead of specific FDA requirements); *Fry*, 695 A.2d, at 513, 516 (overstating limitations on labeling changes after PMA).

it relies on FDA approval, supposed limits on product modification, and continuing FDA oversight. See 20a, 23a, 27a. Those attributes are shared with every case rejecting PMA-based preemption. See, *e.g.*, *Goodlin*, 167 F.3d, at 1368-70. It is true that, with respect to inhalation risks, the Eighth Circuit also emphasized post-approval regulation. Specifically, the FDA directed a study of operating-room inhalation in 1975 and conditioned expanded use of respondents' product on their sending a "Dear Doctor" letter in 1976.[11] But those facts do not meaningfully distinguish this case from anti-preemption rulings. FDA's inquiry into the risk that ultimately befalls the plaintiff is not enough for preemption. See *id.*, at 1370, 1375 and n.14 (describing FDA demands for testing and receipt of research regarding the feared defect that precipitated the plaintiff's surgery, while denying preemptive effect to FDA notices of deficiency and proposed product modifications). Nor is there anything uncommon about post-approval interaction between manufacturers and the FDA. Similar cautionary letters were prompted by FDA in both *Goodlin*, 167 F.3d, at 1369, and *Oja*, 111 F.3d, at 787, 789. Finally, the purported federal obligation to send the letter was discharged years before petitioner's exposure to the product. With respect to a one-time study or mailing, there is no existing "requirement applicable . . . to the device," §360k(a)(1), that can have preemptive force. The split of authority is both real and relevant to the outcome in this case.

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[11] Cf. 6a, 8a, 27a (showing an FDA-prompted alteration in the flammability/volatility warning regarding ventilation, though the sentence addressing respiratory "irritation" did not change).

c. The standard for comparing eligible state and federal requirements. Even if this case involves the type of state and federal requirements that Congress and the FDA identified for preemption purposes, the Court is then presented with the issue of comparison. *Lohr* held that §360k(a) preemption mandates a "careful comparison" of eligible state and federal requirements, 518 U.S., at 500; the mere presence of device-specific state and federal requirements is not enough. Justice Breyer was in accord. Departing from the dissent's expansive reading of the "different from, or in addition to," language in §360k(a)(1), he explained, "Congress could not have intended that the existence of one single federal rule . . . would pre-empt *every* state law" rule directed at the same device. *Id.*, at 505.

What must courts find when making this comparison? At the very least, the state and federal requirements must address the same subject matter. Even the *Lohr* dissenters would not preempt a state *design*-defect claim with a federal *labeling* regulation. See 518 U.S., at 513-14 (O'Connor, J., concurring in part and dissenting in part). The majority confirmed that more is necessary. For example, they looked for state requirements that "threaten[ ] to interfere with a specific federal interest," *id.*, at 500, that are "potentially contradictory," *id.*, at 501, that "would impede the ability of federal regulators to implement and enforce specific federal requirements," *ibid.*, and/or that are "a threat to federal requirements," *ibid.*; see also *id.*, at 489 (plurality opinion) (stating that Congress was "primarily concerned with the problem of specific, conflicting state statutes and regulations"). And Justice Breyer closed his analysis by consulting general principles of conflict and field preemption. *Id.*, at 507-08;

accord *id.*, at 496 (majority opinion) (FDA is uniquely qualified to ascertain whether state law stands as an obstacle to congressional objectives); 21 CFR §808.1(d) (preemption is triggered by "divergent" state requirements). Or as the dissent observed, "[t]he Court holds that [a federal] 'requirement' triggers pre-emption only when a conflict exists between a specific state requirement and a specific [federal] requirement applicable to the particular device." 518 U.S., at 511.

Isolating the standard for comparing state and federal requirements is now a matter of dispute in state and lower federal courts. The division is less pronounced on this subject, given that preemption is often rejected or accepted on broader grounds. Yet specifying the standard is necessary to a complete understanding of §360k(a), and courts have reached meaningfully different conclusions on the matter.

In *Connelly* v. *Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996) (en banc), *cert. dismissed*, 520 U.S. 1260 (1997), the Missouri Supreme Court held that a federal labeling regulation for intraocular lens implants (another class III device) could not preempt common law failure-to-warn claims. *Id.*, at 849-50, 854. Injured consumers had alleged that the manufacturer failed to warn them about unreasonably high complication rates, and the FDA's labeling regulation was obviously device-specific. *Id.*, at 854; see also *id.*, at 850 (noting the product-specific protocol under which the plaintiffs' lenses had entered the market as investigational devices). Yet the court could find no "conflict" between the premises of the plaintiffs' claims and the FDA's mandates. *Id.*, at 854. The manufacturer could comply with both state and federal duties, because "[n]one of the applicable regulations prohibit [the

manufacturer] from notifying physicians or customers of complication rates." *Ibid.* The court acknowledged that the statute required product labels to be submitted to FDA, and that the agency had promulgated a labeling regulation "specifically for intraocular lenses." *Ibid.* But again, "[n]othing in those regulations prohibits [the manufacturer] from adding a warning to the label regarding unreasonably high complication rates." *Ibid.*

Under Missouri's actual-conflict approach, respondents' preemption defense must be rejected. Any FDA warning requirements are minimum, even provisional, standards. FDA rules endorse warning enhancements, which may be implemented before FDA approval. See 21 CFR §814.39(d)(2)(i)-(ii). And on the record of this case, the FDA has not considered (much less opposed) enhanced warnings, more detailed warnings, or other means of warning product users about the injury suffered by petitioner. Of course, if FDA had actually rejected a warning change mandated by petitioner's theory of recovery at trial, then *Connelly*'s test would be satisfied. But that is not this case. See also *Niehoff* v. *Surgidev*, 950 S.W.2d 816, 822-23 (Ky. 1997) (following *Connelly*), *cert. denied*, 523 U.S. 1005 (1998); *Goodlin*, 167 F.3d, at 1373 n.8, 1374 n.13, 1376.

In contrast, federal courts in Missouri and in the rest of the Eighth Circuit are now obligated to preempt in a wider range of circumstances. The court below relied not on actual conflict between an FDA prohibition and the alleged effect of a tort judgment in petitioner's favor, but rather on FDA's ongoing regulation in the field of operating-room safety. See 20a-21a (discussing *Martin* v. *Medtronic, Inc.*, 254 F.3d 573,

582, 584-85 (CA5 2001), *cert. denied*, ___ U.S. ___, 122 S.Ct. 807 (2002), *Kemp*, 231 F.3d, at 230, 236, and *Mitchell*, 126 F.3d, at 913-14). As the Eighth Circuit put it, "[t]he failure to warn claim [petitioner] seeks to assert *could* impose state requirements which conflict or interfere with" the specific federal requirements identified by the court. 27a (emphasis added).

But there is no cause for courts to speculate. FDA is quite capable of expressing its intent to foreclose product alteration and preempt state law, either within its warning-enhancement procedure or elsewhere. Absent a clear statement or square conflict, the judiciary should avoid substituting its judgment for the agency's – and for the States'. See *Lohr*, 518 U.S., at 507 (Breyer, J., concurring in part and concurring in judgment) (rejecting express preemption by asserted numerosity of federal requirements); *Hillsborough County*, 471 U.S., at 717-18 (rejecting implied-field preemption by comprehensiveness of FDA regulation). The Eighth Circuit's policy assault on tort suits and juries in favor of centralized decision making, see 24a-25a – and, incidentally, the elimination of consumer compensation – suggests how far some courts are willing to stretch federal preemption to "reform" state law.

The decision below devalues federalism and mistakes agency action on one front for a prohibition on all others. "There is no inherent conflict between regulation of devices by the FDA (including the . . . PMA process[ ]) and state law tort claims . . . . " U.S. Br. in *Kernats* at 13.

3. Timing questions. As noted, the product at issue received initial approval for marketing as a new

"drug" in 1971, before the PMA process for devices became law in 1976. Below petitioner argued that neither approval process was preemptive, but she also contended that the product's initial status as a "drug" was an additional ground for denying respondents' defense. That additional argument is not a vehicle problem. First, petitioner abandons it here. Second, initial NDA approval made no difference to the court of appeals in light of the product's classification as a class III medical device with PMA in 1976; and no other court has reached a different conclusion. In fact petitioner, respondents, and the lower courts agreed that the PMA and NDA processes are comparable and equally "rigorous" for purposes of analyzing express federal preemption. 4a-5a, 71a. Perhaps most important, the MDA includes a provision stating that after 1976 products like the one at issue here must be treated as class III medical devices with PMA. See 4a, 6a; 21 U.S.C. §360j(l)(1)(A), (3)(A); H.R. Conf. Rep. No. 94-1090, p. 62 (1976) (explaining that such products would thereafter be regulated as devices with PMA); 42 Fed. Reg. 63,472 (1977). The arguments for and against preemption in this case are unrelated to the label of the initial FDA approval process.

Additionally, in late 1999 and after the district court granted summary judgment, FDA agreed to reclassify polymethyl-methacralate bone cement from class III to class II. Reclassification Order, Docket No. 98P-0035 (Oct. 14, 1999). That fact should not be a bar to review here. First, respondents waived any preemption defense based on the product's current legal classification, see Respondents' Brief at 5 n.4, *Brooks* v. *Howmedica, Inc.*, 236 F.3d 956 (CA8 2001) (No.

00-1188); their contentions rested on PMA-based preemption cases. Second, reclassification was irrelevant to the court of appeals because it took place "at a time after the period during which [petitioner] was exposed to" the product. 7a n.5; see also 12a. There may be some room for debate about whether product exposure is a premature point in time at which to test for §360k(a) preemption. Cf. *Lohr*, 518 U.S., at 504-05 (Breyer, J., concurring in part and concurring in judgment) (offering the liability-creating premise of an adjudicated lawsuit as a potential source of specific state requirements). But here the parties and the lower court accepted the time of exposure as appropriate. It is, after all, a period during which respondents could have done something more to warn petitioner before the damage was done. Cf. *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 881 (2000) (assessing the regulatory effect of state tort law at the time of manufacture – *i.e.*, when the alleged state duty was breached).

Finally, there is no substantial argument for percolation in light of *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). That decision provides no useful guidance on the question presented. *Buckman* considered only implied preemption of a "fraud on the FDA" claim against a consulting company. The Court "express[ed] no view" on the scope of §360k, *id.*, at 348 n.2, which is the only issue in this case.[12] Moreover, the *Buckman* plaintiffs' only claim was "fraud on

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[12] Respondents waived any implied-preemption defense by failing to raise it in the trial court. In supplemental briefing to the full Eighth Circuit, respondents discussed implied-preemption principles only in response to petitioner's assertion that no conflict existed between any eligible state and federal requirements. See Respondents' Supplemental Brief at 5-9, *Brooks*

the FDA." It rested solely on the defendant's alleged violation of a federal duty running to the FDA. *Id.*, at 343, 347-48, 352-53. The plaintiffs could not rely on a traditional state tort recognized before the federal regulatory regime was enacted. So *Buckman* itself distinguished *Lohr*, because the claims in the latter "arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of [Food, Drug, and Cosmetic Act] requirements." *Id.*, at 352. Of course the same factors distinguish this case: Petitioner asserts that respondents breached longstanding common law duties to warn and instruct *her*, duties that the FDA has no authority to enforce by compensation. *Buckman* is inapposite, and lower courts understand that. See *Green* v. *Fund Asset Management, L.P.*, 245 F.3d 214, 222-23 n.7 (CA3 2001) (recognizing *Buckman*'s limits and rejecting an implied-preemption defense under the Investment Company Act of 1940).

The question presented is important to consumers, to manufacturers, to the States, and to federal policy. Numerous courts have confronted §360k, and they do not and will not willingly agree about its application to state law damages claims. Petitioner understands that this Court is not obligated to act. But delay will only make matters worse.

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v. *Howmedica, Inc.*, 273 F.3d 785 (CA8 2001) (No. 00-1188). Regardless, no court has endorsed implied preemption in this context, see *Goodlin*, 167 F.3d, at 1371 n.5; *Webster*, 171 F. Supp. 2d, at 12-14, and its theoretical possibility is no reason for refusing to resolve the important and well-vetted question presented here.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 00-1188

Carol Jean Brooks,

Plaintiff-Appellant;

St. Luke's Hospital,

Intervenor Below,

v.

Howmedica, Inc., a Delaware Corporation, Division of Pfizer Hospital Products Group, Inc.; Pfizer, Inc.; Howmedica International, Ltd.,

Defendants-Appellees.

Product Liability Advisory Council, Inc.,

Amicus on Behalf of Appellees.

Appeal from the United States District Court for the District of Minnesota.

Submitted: July 10, 2001
Filed: December 11, 2001

Before WOLLMAN, Chief Judge, HEANEY, McMILLIAN, BOWMAN, LOKEN, HANSEN, MORRIS SHEPPARD ARNOLD, MURPHY, and BYE, Circuit Judges.

MURPHY, Circuit Judge.

Carol Jean Brooks brought this action against the manufacturer of Simplex bone cement claiming damages for injury resulting from its failure to give adequate warnings about product dangers. The case was dismissed on summary judgment after the district court[1] concluded that her claim was preempted by federal law, § 360k of the 1976 Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et. seq. A panel of this court reversed with one judge dissenting, *Brooks v. Howmedica, Inc.*, 236 F.3d 956 (8th Cir. 2001), a petition for rehearing en banc was granted, and the panel opinion was vacated. After examining the record and considering *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), we affirm the judgment of the district court.

I.

Carol Jean Brooks is a licensed practical nurse whose work as a surgical technician included mixing bone cement. Bone cement is used to bond with a bone or prosthesis in orthopedic surgeries, including joint replacements. Brooks began mixing bone cement during 1978 while she worked at St. Mary's Hospital in Duluth, Minnesota, but her principal exposure occurred after she moved to St. Luke's Hospital in Duluth in 1982. At St. Luke's she initially participated in a variety of surgeries, but in 1983 she began to assist almost exclusively in

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[1] The Honorable Michael J. Davis, United States District Judge for the District of Minnesota.

orthopedic surgeries, mixing bone cement or being present during its preparation approximately four times a week. By 1992 she was mixing bone cement or was close to the mixing process during approximately ten surgeries a week. Although Brooks is unable to identify the brand of bone cement used at St. Mary's, it is undisputed that St. Luke's used Simplex P Radiopaque bone cement (Simplex), which was manufactured and marketed by appellees (collectively Howmedica).[2]

Brooks began to cough at some time in 1989 or 1990. She went to see a doctor about it in 1991 when she was told she had asthma. An occupational health physician at St. Luke's Hospital also investigated possible causes for her cough, reviewed Howmedica's Material Safety Data Sheet, and talked with a Howmedica chemist, but that investigation did not link her cough to Simplex. St. Luke's restricted her exposure to a number of chemicals after an acute asthma attack in 1992; the restriction included methyl methacrylate which is an ingredient in Simplex. Brooks was later diagnosed to have occupational asthma caused by exposure to methyl methacrylate. Brooks has been unable to work since 1995.

Brooks brought a failure to warn claim against Howmedica, alleging that it had not provided "adequate

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[2] At the time this action was commenced, defendants Howmedica Inc. and Howmedica International, Ltd. were wholly owned subsidiaries of defendant Pfizer, Inc. The record does not make clear which corporate entity was responsible for manufacturing or selling Simplex during the time Brooks was injured, but none of the appellees has challenged its status as a defendant.

warnings and instructions" for Simplex use and that as a result, she had contracted "severe asthma and associated respiratory complications." Howmedica asserted federal preemption and also denied that the Simplex label contained inadequate warnings and instructions or that it proximately caused Brooks' injury. St. Luke's Hospital intervened, seeking compensation from Howmedica for what it had paid Brooks in workers compensation benefits, costs, interest, disbursements, and attorney fees, but it is not involved in this appeal.

II.

Starting in the early 1970's Howmedica began to market bone cement in the United States under the trade mark Simplex. Bone cement is sold in two separately packaged components: methyl methacrylate monomer which is a colorless liquid and a powder mixture containing polymethyl methacrylate, methyl methacrylate styrene copolymer, and barium sulfate. The liquid and powder are mixed together in the operating room to form a pliable mass that later hardens into a cement like consistency. The mixing process releases vapors containing methyl methacrylate, which is classified as a hazardous chemical by the Occupational Safety and Health Administration.

It is undisputed that Simplex has been heavily regulated by the FDA since it entered the market when it was treated as a drug subject to the Federal Food, Drug, and Cosmetic Act of 1938 (1938 Act). The 1938 Act required Howmedica to submit a New Drug Application (NDA)

before it could sell Simplex,[3] *see* 21 U.S.C. § 355, and the NDA is a rigorous process. The NDA process required Howmedica to disclose details of animal studies, manufacturing and quality control procedures, the identification of possible side effects, results of clinical trials, summaries of surgical cases and post operative complications, long term toxicity, and carcinogenicity studies. The process also produced reports from the investigational use of Simplex by sixty seven physicians in 1,408 hip replacements which involved 2,800 preparations of the product. All these submissions were then studied and reviewed by a panel of FDA experts. Under the 1938 Act, Simplex could not be marketed without approval by the Secretary of Health and Human Services. *See* 21 U.S.C. § 360(c) (premarket approval process).

The NDA included review by the FDA of the proposed design and content for all Simplex labels, including labels for a vial, a pouch, two internal boxes, an outer box, and a package insert. Howmedica employees met with members of the FDA on several occasions to discuss its application, including the product labels. The FDA reviewed every word that appeared on Simplex labels, and the FDA drafted the language that was used in the package insert. That package insert included the following warning:

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[3] Howmedica developed and submitted NDAs for two types of Simplex. The only difference between the two is that one type was detectable on x-ray and the other was not. The approval process was identical for both types, and neither side in this case differentiates between the two.

> As the liquid monomer is highly volatile and flammable, the operative room should be provided with adequate air circulation. Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated vapors of the monomer which may produce irritation of the respiratory tract, eyes, and possibly the liver.

The vial containing the liquid component and the box with the powder both referred the user to the package insert for information regarding dosage and administration.

Simplex was approved by the FDA for use in total hip replacement surgeries in 1971. The FDA wrote "[w]e have completed the review of this application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved."

These review requirements were affected by the 1976 Medical Device Amendments (MDA) to the 1938 Act. The MDA created three classes of medical devices, categorized by the risk to the public and the degree of regulation required. Class I devices present no unreasonable risk of illness or injury and are subject only to "general controls." 21 U.S.C. § 360c(a)(1)(A). Class II devices present greater risk than those in Class I, and they must comply with federal performance regulations called "special controls" but may be marketed without advance approval. *Id.* at § 360c(a)(1)(B). Class III devices carry "a potential unreasonable risk of illness or injury," or are used for "supporting or sustaining human life," or are seen to be "of substantial importance in preventing

impairment of human health." *Id.* at § 360c(a)(1)(C). Class III devices are highly regulated and must receive premarket approval (PMA) from the FDA before they may be sold. *Id.* at § 360e(a).[4]

Devices such as Simplex, which had been treated as drugs prior to the amendments to the 1938 Act, were automatically reclassified by the MDA as Class III medical devices.[5] *See* 21 U.S.C. § 360j(*l*)(1). The statute provided that these devices were deemed to have PMA approval if they had gone through the NDA approval process. *Id.* at § 360j(*l*)(3)(A). Beginning in 1976 Simplex was accordingly treated as a Class III medical device with PMA approval.

Under both the 1938 Act and the MDA, the FDA has continuing authority and responsibility to control the content of any information or warnings Howmedica provides Simplex users. Howmedica was required to provide the FDA with regular reports of any new information learned about Simplex. *See* 21 U.S.C. § 355(k); 21 C.F.R. §§ 314.80, 314.81, 814.84 (2000). The company was not permitted to make any changes to the product label affecting the safety or effectiveness of the device without submitting a supplemental PMA, but it could temporarily "add or strengthen" warnings during the time the FDA

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[4] There are certain exemptions to the PMA requirement which do not apply to Simplex but are discussed in *Kemp v. Medtronic*, 231 F.3d 216, 221-22 (6th Cir. 2000).

[5] The FDA later reclassified bone cement from a Class III device to Class II, but that was at a time after the period during which Brooks was exposed to Simplex.

had any supplement under consideration. 21 C.F.R. § 814.39(a), (d) (2000).

Howmedica learned that some individuals exposed to Simplex had developed contact dermatitis, and in 1973 it requested permission from the FDA to insert the following language into its warnings: "The liquid component is a powerful lipid solvent, and may also act as a sensitizer in certain individuals." After its consideration of the request, the FDA decided to direct Howmedica to revise its package insert to include this additional language:

> The liquid component is a powerful lipid solvent. It has caused contact dermatitis in susceptible individuals. Wearing of a second pair of surgical gloves and strict adherence to the mixing instructions may diminish the possibility of hypersensitivity reactions. The compound should not be allowed to come into direct contact with sensitive tissues or be absorbed by the body.

In 1975, the FDA required bone cement manufacturers to participate in a review of the inhalation toxicity of methyl methacrylate vapors, and the Simplex warnings were reexamined. After a number of discussions, the FDA required Simplex to modify the package insert warnings concerning vapor inhalation as follows:

> As the liquid monomer is highly volatile and flammable, the operating room should be provided with adequate ventilation so as to eliminate the maximum amount of monomer vapor. Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated vapors of the

> monomer which may produce irritation of the respiratory tract, eyes, and possibly the liver.

The FDA also directed Howmedica to send a "Dear Doctor" letter to Simplex users to warn about inhalation hazards associated with methyl methacrylate. Howmedica told the FDA it believed the letter was unnecessary because studies had shown that the concentration of methyl methacrylate vapors in operating rooms was within accepted limits, but the FDA insisted on compliance with its directive. Howmedica and the FDA then worked together to draft the letter, which directed attention to methyl methacrylate vapor inhalation studies and to the package insert warning. It also recommended that hospital facilities be inspected for adequate ventilation. The final paragraph of the letter warned:

> In some sensitive individuals, exposure to MMA can cause dermatitis and other allergenic responses. If any of your operating room personnel develop such responses when using Simplex®, both prudence and good medical practice would suggest that they avoid all procedures involving use of Simplex®.

Howmedica sought to expand the uses of Simplex, and in March 1976 the FDA approved its request from the previous year to use the product in fixing pathological fractures. The FDA approved the request with the condition that Howmedica send the "Dear Doctor" letter to members of the American Academy of Orthopaedic Surgeons and to all hospital administrators and operating room supervisors at hospitals and clinics which had recently purchased Simplex. In July, Howmedica submitted a supplemental NDA to seek approval of Simplex use

in elbow, wrist, ankle, shoulder, and finger joint replacement surgery. During this application process, the FDA again reviewed Simplex labels and required specific changes be made to reflect these uses. After Howmedica had made the required labeling changes, the FDA approved the application.

In 1986, Howmedica received information that soft contact lenses could be damaged by methyl methacrylate vapors and requested that additional warnings be added to Simplex labels. The FDA approved the addition of the following warning:

> It has been recommended by manufacturers of soft contact lenses that such lenses should be removed 'in the presence of noxious and irritating vapors.' Since soft contact lenses are quite permeable, they should not be worn in an operating room where methyl methacrylate is being mixed.

This addition was the final adjustment made to the Simplex warning related to occupational use during the period when Carol Brooks was exposed to the product.

III.

After discovery was complete in the district court, Howmedica moved for summary judgment. It argued that Brooks' failure to warn claim was preempted by the MDA because she sought to impose a requirement on Simplex that was different from, or in addition to, federal requirements developed through the NDA process. It also argued that any inadequacy in Simplex warnings was not

the proximate cause of Brooks' injury because she admitted she had never read the product labels or package insert. Brooks argued that her claim was not preempted because the duty to warn is a general obligation applicable to all devices, and approval by the PMA or NDA does not impose specific federal requirements with preemptive effect. She also asserted at this time that Howmedica had failed to comply with general FDA labeling regulations although she had not pled such a claim in her complaint.

The district court granted Howmedica's motion and dismissed the case. After a comprehensive discussion of the relevant case law, the court concluded that even if Brooks could show that her injury had been caused by Howmedica's failure to provide her with adequate warnings and directions for use, her failure to warn claim was preempted by federal law and that she had not submitted sufficient support for any claim that Howmedica failed to comply with FDA rules or regulations.

Brooks appealed, arguing that her general common law duty to warn claim was not preempted and that the NDA and PMA are not specific federal requirements with preemptive force. She also argued that Howmedica's alleged breach of its duty under common law amounted to a violation of general FDA labeling requirements. Howmedica responded that Simplex is deemed under the MDA to have PMA approval and that the PMA has been recognized by this court to be a federal requirement with preemptive effect, citing *Martello v. Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994). It argued that Brooks' claim was a state requirement different from, or in addition to, the federal requirement and therefore preempted under § 360k of the MDA. Howmedica also argued that Brooks

had provided no evidence that it had violated any FDA rules or regulations. Both sides contended that the Supreme Court's decision in *Medtronic v. Lohr*, 518 U.S. 470 (1996), favored their respective positions.

A panel of this court reversed the dismissal of the failure to warn claim, with one judge dissenting. *Brooks v. Howmedica, Inc.*, 236 F.3d 956 (8th Cir. 2001). The majority interpreted *Lohr* to permit the claim to go forward, holding that the claim would not result in any actual conflict between state common law and federal requirements and was therefore not preempted. *Id.* at 964-66. The dissent pointed out that the device at issue in *Lohr* had been approved through a much less rigorous process than the PMA and the NDA review of Simplex, and that during the regulatory process for Simplex the FDA had considered a particular federal requirement, had concluded how competing considerations regarding that requirement should be resolved, and had imposed a specific mandate on Howmedica to that end. *Id.* at 967. The panel treated Brooks' allegation that Howmedica had not complied with FDA regulations as a common law negligence per se claim and affirmed its dismissal. *Id.* at 966-67.

Howmedica's petition for rehearing en banc was granted, and the panel opinion was vacated. The parties submitted additional briefs, and the Product Liability Advisory Council, Inc. was given permission to submit an amicus brief.[6] At oral argument, the parties advanced

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[6] In its brief the Product Liability Advisory Council asserts that Brooks' claim is preempted under the MDA. It argues that neither state nor federal requirements need to be "device-specific" in order to warrant federal preemption and that

substantially the same points they had made earlier, but Brooks put increased emphasis on her contention that the link between methyl methacrylate and occupational asthma had not been made until 1985. She asserts that the product warning was not changed in response to the publication in 1985 of two articles linking methyl methacrylate and occupational asthma and that it is not clear that the FDA ever considered such a risk. Howmedica responds that the FDA decided on the wording of the warnings for the Simplex package insert with full awareness of the respiratory risks.

IV.

A grant of summary judgment is reviewed de novo. *United States v. Scherping*, 187 F.3d 796, 800 (8th Cir. 1999). Summary judgment is proper when there is no genuine issue of material fact and the moving party would be entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). Brooks contends that her state claim for failure to warn is not preempted under the MDA, and she also advances an argument that she has a state claim of inadequate labeling which "parallels" federal labeling requirements. Howmedica responds that the district court correctly dismissed the claims on summary judgment.

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permitting claims such as the one alleged by Brooks would cause "over-warning" injurious to the FDA's regulatory goals and to the public health.

A.

State law which conflicts with federal law is preempted under the Supremacy Clause of the Constitution. U.S. Const., Art. VI, cl. 2. Congressional intent to preempt state law can either be expressed in statutory language or implied in the structure and purpose of federal law. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992).[7] At the time Carol Brooks was exposed to Simplex, the product was regulated as a Class III device under the MDA, which contains an express preemption provision, codified at 21 U.S.C. § 360k:

> (a) [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> > (1) which is different from, or in addition to, any requirements applicable under this [Act] to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter

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[7] Howmedica asserts that Brooks' failure to warn claim is expressly preempted by § 360k, but on appeal it has also argued in the alternative that her claim is impliedly preempted under federal law. Because we find express preemption, we do not address any potential issue of implied preemption. We notice parenthetically, however, that the Supreme Court recently held that state law claims of fraud on the FDA are impliedly preempted under federal law, "express[ing] no view" on whether such claims are subject to express preemption under § 360k. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 348 n.2 (2001).

> included in a requirement applicable to the device under this [Act].

21 U.S.C. § 360k.

At first glance the preemption issue presented here under § 360k might seem quite simple since the state law result sought by Brooks relates to safety and would impose different or additional requirements on the product warning for Simplex. That the issue is not so simple is evidenced by *Medtronic, Inc. v. Lohr.* 518 U.S. 470 (1996), a case in which a sharply divided Supreme Court interpreted § 360k.

Lohr involved claims relating to the design, manufacture, and labeling of a pacemaker, including claims for common law failure to warn and violation of FDA regulations. *Id.* at 481, 495. The manufacturer unsuccessfully attempted to persuade a majority of the Court that Lohr's failure to warn claim was barred by the MDA preemption provision. The Court split, with Justice Breyer the swing vote as he joined first one group of justices, then the other. Justice Stevens, writing for a four justice plurality, stated that § 360k would rarely, if ever, preempt state common law claims. *Id.* at 502. Justice O'Connor on behalf of four dissenting justices disagreed, believing that § 360k preempts any state requirement – including a common law duty – that is "different from, or in addition to" a federal requirement. *Id.* at 514. Justice Breyer agreed with Justice O'Connor that state common law claims can be subject to preemption under § 360k, *id.* at 503, but he joined Justice Stevens and the plurality in ruling on Lohr's claim for failure to warn.

In a part of the opinion written by Justice Stevens and joined by Justice Breyer, the *Lohr* Court examined the regulations promulgated by the FDA which contain the agency's interpretation of § 360k:

> (d) State or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements. . . .
>
> (1) [§360k] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices . . . or to unfair trade practices in which the requirements are not limited to devices.
>
> . . . .
>
> (6)(ii) Generally, [§360k] does not preempt a State or local requirement prohibiting the manufacture of . . . misbranded devices [unless] such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, [that is] different from, or in addition to, a Federal requirement established under the act. . . .

21 C.F.R. § 808.1(d) (2000). These regulations attempt to clarify the intended meaning of the statutory language, and the *Lohr* Court said it was "substantially informed" by them. 518 U.S. at 495.

Drawing on the statute and the regulations, the Stevens majority in *Lohr* described a series of requirements necessary for a finding of preemption under the MDA. State requirements are preempted only if they relate to "the safety or effectiveness of the device" or to another matter included in a requirement applicable to the device. *Id.* at 500. State requirements must be "with respect to" medical devices, and state requirements of "general applicability" are subject to preemption only if they have the effect of establishing a substantive requirement for a specific device. *Id.* Federal requirements must also be "applicable to the device" at issue; that is, they must be "specific counterpart regulations" or specific to the particular device. *Id.* State law will be preempted under the MDA when "a particular state requirement threatens to interfere with a specific federal interest." *Id.*

The Court concluded that Lohr's failure to warn claim was too general to require preemption. *Id.* at 502. Although the duty to inform users of potential product dangers applies to all manufacturers, this general duty was "not specifically developed 'with respect to' medical devices." *Id.* at 501. Medtronic's duty to warn in respect to the pacemaker was not the kind of "requirement[ ] that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements." *Id.*

If some of the language in *Lohr* were read without careful consideration of the separate opinions, it might imply that no state tort claim could ever be preempted since each is based on broadly applicable common law duties. Such a reading would directly contradict the view of a separate majority of the Court, however, for five

justices concurred in Justice O'Connor's statement that § 360k "clearly preempts any state common-law action that would impose a requirement different from, or in addition to" a specific federal requirement. *Id.* at 511. *See also id.* at 503 (Breyer, J., concurring).

The crux of the disagreement in *Lohr* between the Stevens majority and the dissenters is the meaning to be given to the statutory phrase "a requirement different from, or in addition to." *Lohr* instructs that state requirements – including common law duties – are preempted to the extent that they interfere with specific federal requirements. The state and federal restrictions must be "carefully compar[ed]" to ascertain whether there is interference between them – that being the "overarching concern" of the test articulated by Justice Stevens and joined in by Justice Breyer. *Id.* at 500. A state claim will be preempted in circumstances where "a particular state requirement threatens to interfere with a specific federal interest." *Id.* In his concurring opinion Justice Breyer phrased the issue as whether an "actual conflict" exists between the state and federal requirements, *id.* at 508,[8] and that opinion deserves close attention since his vote

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[8] In his opinion Justice Breyer cited earlier Supreme Court cases describing "conflict" preemption. 518 U.S. at 507. Among the cases he cited was *Gade v. Nat'l Solid Wastes Mgmt. Ass'n.*, 505 U.S. 88 (1992), which explained that a state requirement is preempted if it actually conflicts with a federal requirement, either because compliance with both is impossible or because the state requirement "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* at 98 (1992) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

created the majority. The key question before the court is whether the specific state requirement Brooks wishes to impose on Simplex would interfere with a specific federal requirement, but the question may also be phrased as whether the specific state and federal requirements conflict.

In *Lohr*, the plaintiff's failure to warn claim did not conflict with the federal requirements imposed on the Medtronic pacemaker. The product had received FDA approval through a system intended to allow rapid introduction of improvements to existing devices. *Id.* at 478. Under the § 510(k) process[9] involved in *Lohr*, a device can be sold without PMA approval if it is "substantially equivalent" to one already on the market. *See* 21 U.S.C. § 360e(b)(1)(B); 21 C.F.R. 814.1(c)(1) (2000). A substantially equivalent device is examined in the § 510(k) process only for similarities with existing devices; safety and effectiveness are not the focus. *Lohr*, 518 U.S. at 493. Section 510(k) approval is a mere grant to market; it imposes no "requirements" of its own. *Id.* at 493-94. The pacemaker there was subject to a federal regulation requiring Medtronic to provide a label indicating "any relevant hazards, contraindications, side effects, and precautions." 21 C.F.R. § 801.109(c) (2000). This requirement applied to all manufacturers in the industry and reflected generic concerns about device regulation. It did not require the FDA to be involved in the drafting or approval of the pacemaker's product label. The requirement was not specific, and a common law claim would

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[9] The type of process established under § 510(k) of the MDA as enacted in 1976.

not "impede the ability of federal regulators to implement and enforce" it. 518 U.S. at 501.

The facts in the case before the court are very different from those in *Lohr*. The FDA drafted or approved every word of the Simplex label, and any changes were subject to close FDA scrutiny. PMA review typically requires 1,200 hours of rigorous testing for device safety. In contrast, § 510(k) review focuses on "substantial equivalence" and is completed in an average of twenty hours. *Id.* at 479. The two processes are "by no means comparable." *Lohr*, 518 U.S. at 478.

B.

Our court considered the preemptive effect of the MDA in a decision predating *Lohr*, *Martello v. Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994). In *Martello*, we held that the PMA is a specific federal requirement within the meaning of § 360k which preempts state court claims involving safety "when the claims would impose additional requirements in areas [it has] regulated." *Id.* at 1169. Under *Lohr* this holding requires some modification because common law claims are only preempted to the extent that they threaten to interfere with specific federal requirements. 518 U.S. at 501-02.

Most courts of appeal have interpreted *Lohr* to mean that the MDA preempts common law claims to the extent that they interfere or conflict with specific federal requirements. *See, e.g., Martin v. Medtronic Inc.*, 254 F.3d 573, 582 (5th Cir. 2001); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 230 (6th Cir. 2000); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 913-14 (7th Cir. 1997); *Papike v. Tambrands, Inc.*, 107

F.3d 737, 742 (9th Cir. 1997). *But see Oja v. Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1997) (common law failure to warn claim is not subject to preemption under the MDA). *Martin, Kemp,* and *Mitchell* all considered failure to warn claims involving products which had had a full PMA like that undergone by Simplex. The Fifth Circuit in *Martin* concluded that a general duty of care under state law is preempted if "the elements needed to prove [its] violation" are specific and "therefore threaten specific federal requirements." 254 F.3d at 582. Because the design of the *Martin* product label had been approved by the FDA through the PMA process, a failure to warn claim would impose state requirements that would conflict with specific federal requirements and it was therefore preempted. *Id.* at 584-85. Similarly, the Sixth Circuit in *Kemp* held that a common law claim is preempted if it would add "different" or "additional" elements to specific federal requirements approved through the PMA. 231 F.3d at 236. The Seventh Circuit also concluded in *Mitchell* that when a manufacturer has adhered to the PMA process, a common law claim of mislabeling is preempted because it would impose "different" or "additional" requirements. 126 F.3d at 913-14. *Cf. Papike,* 107 F.3d at 742 (failure to warn claim preempted by FDA labeling regulations regarding toxic shock syndrome).

Those circuit court decisions since *Lohr* which have not found preemption in failure to warn cases were faced with circumstances different from those in this case. In *Oja,* the Tenth Circuit held that a common law duty to warn is not a "substantive requirement" subject to preemption, but that case involved approval through an

investigational device exemption, a considerably less rigorous process than the full PMA. 111 F.3d at 786-87, 789. In *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), a case in which the FDA had issued no statement or order of requirements beyond review and approval of the initial PMA, the Eleventh Circuit ruled that simple approval of the PMA application imposes no federal "requirements." *Id.* at 1375. The *Goodlin* court implied, however, that it would find preemption in a case involving an "ascertainable requirement in an express FDA" order or regulation. *Id.* (citing *Papike*, 107 F.3d at 740-41). That is what we have here, where the FDA has issued a series of specific mandates regarding the label for Simplex. Simplex has been subject to continuing and specific FDA regulation, beyond its initial approval through the PMA process.

C.

The failure to warn claim asserted by Brooks would interfere or conflict with the specific federal requirements imposed during the regulation of Simplex. A jury finding of negligent failure to warn would be premised on the fact that the label for Simplex was not written in a particular way or did not contain certain information. This would be equivalent to a state regulation imposing specific label requirements. Justice Breyer illustrated this principle in his concurring opinion in *Lohr* when he pointed out that if a jury were to find negligence in the use of a wire longer than one inch in the manufacture of a hearing aid when the FDA had required a two inch wire, there

would be federal preemption as surely as if a state regulation were to impose such a limitation. *Id.* at 504 (Breyer, J., concurring).[10]

The effect of a jury finding of negligent failure to warn would be that state law would require Howmedica to change the label and package insert for Simplex, but Howmedica may not unilaterally make such changes under federal law. A device may not be labeled in a manner inconsistent with any conditions specified in its PMA. 21 C.F.R. § 814.80 (2000). A manufacturer must submit a Supplemental PMA for any proposed labeling changes that affect the safety of the device. *Id.* at § 814.39(a). Brooks points out that the regulations permit manufacturers to make temporary changes in the interest of safety, *see id.* at § 814.39(d), but such changes are valid only after the manufacturer has submitted a Supplemental PMA and only during the pendency of that application. *Id.* at § 814.39(a)(2), (d)(1). Once the Supplemental PMA has been approved, modified, or denied, the manufacturer must comply with the FDA's decision. *Id.* at § 814.80.

Brooks argues that limiting the warnings on a label would not seem to advance the FDA's purpose to ensure device safety. There are, however, a number of sound

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[10] *See also Martin*, 254 F.3d at 582-83; *Kemp*, 231 F.3d at 237 (Moore, J., concurring). Also illustrative is the report of one of Brooks' experts (Frank Junghans), which proposed revisions to the label, safety sheet, and package insert for Simplex, including additional language and colorful pictographs. A jury might adopt any of his suggestions as a state requirement after a trial on a common law claim.

reasons why the FDA may prefer to limit warnings on product labels. Warnings about dangers with less basis in science or fewer hazards could take attention away from those that present confirmed, higher risks. A label with many varied warnings may not deliver the desired information to users. Space on product labeling material is also a factor, and the most effective labels are those with large, bold warnings and a simple design. *See generally* Ctr. for Devices & Radiological Health, U.S. Dep't of Health & Human Servs., *Guidance on Medical Device Patient Labeling: Final Guidance for Industry and FDA Reviewers* 42 (2001), *available at* <www.fda.gov/cdrh/ohip/guidance/1128.pdf>. *See also* Richard M. Cooper, *Drug Labeling and Products Liability: The Role of the Food & Drug Administration,* 41 Food, Drug & Cosm. L.J. 233, 237-38 (1986). The FDA's enabling statute also reflects these concerns: warnings must be "prominent[ ]" and "conspicuous[ ]," as compared with other material on the label. 21 U.S.C. § 352(c).

The arguments advanced by Brooks ignore the need for national uniformity in product regulation, one of the explicit goals of the MDA. The legislative history indicates that this was the reason the preemption provision was included within the MDA. H.R.Rep. No. 853, 45 (1976) ("[I]f a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened."). The state requirement in this case would come from a common law duty as applied by an individual jury. Trials of tort claims pose incentives to overwarn: "the visible monetary costs of additional warnings are typically quite low – a few

pennies for a bit more paper and a little more ink." James A. Henderson & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. Rev. 265, 297 (1990). It would be difficult for a jury focused on a single case to take into account "the cumulative, systemic effects" of a series of verdicts. Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 Geo. L.J. 2167, 2175 (2000). In contrast, the FDA possesses a broader perspective. Regulation by the FDA allows the agency to craft labels that maximize safety and effectiveness.

Brooks also claims that an alleged link between methyl methacrylate and occupational asthma first became known in 1985, well after the original FDA approval of Simplex in 1971. She suggests that the FDA did not consider such a danger nor impose any warning requirement with respect to it. She bases this argument on the fact that two articles appeared in 1985 which describe case studies linking methyl methacrylate and occupational asthma and one claimed there had been no previous published report of the chemical's association with asthma. S. Lozewicz et al., *Occupational asthma due to methyl methacrylate and cyanoacrylates*, 40 Thorax 836, 836 (1985). Neither of the two experts put forward by Brooks nor the cited articles claimed, however, that the risk of respiratory irritation from methyl methacrylate had not been previously appreciated, and the product labeling for Simplex and the "Dear Doctor" letter are evidence to the contrary.[11]

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[11] There is evidence that even by 1998 a specific connection between methyl methacrylate and occupational asthma had not

The record demonstrates that the FDA was aware of a possible link between methyl methacrylate and respiratory damage for several decades, and the agency required Howmedica to take specific steps in response. The label for Simplex incorporated the danger of sensitivity to vapors from the very beginning. When Simplex was introduced in 1971, the FDA drafted a package insert which warned that the liquid methyl methacrylate used in mixing is "highly volatile" and that the mixing process required both "adequate air circulation" and caution "to prevent excessive exposure to the concentrated vapors" which could produce "irritation of the respiratory tract." In 1973 Howmedica requested permission to add to the warning to indicate that the ingredients of the product could "act as a sensitizer," but the FDA decided on different wording, requiring a warning about "strict adherence to the mixing instructions" to "diminish the possibility of hypersensitivity reactions" and to prevent absorption of the product.

The FDA conducted an official review of the inhalation toxicity of methyl methacrylate vapors by operating room personnel in 1975, and it subsequently directed Howmedica to send a "Dear Doctor" letter to Simplex users drafted by both Howmedica and the FDA. The letter directed user attention to methyl methacrylate

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been conclusively established. *See* World Health Organization, et al., Concise International Chemical Assessment Document No. 4, Methyl Methacrylate 5 (1998) ("Although occupational asthma associated with methyl methacrylate has . . . been reported, there is no conclusive evidence that methyl methacrylate is a respiratory sensitizer.")

vapor inhalation studies and to the package insert warning and recommended that user facilities be inspected for adequate ventilation. The FDA also mandated changes in the package label. The new version read:

> As the liquid monomer is highly volatile and flammable, the operating room should be provided with adequate ventilation so as to *eliminate the maximum amount of monomer vapor. Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated vapors of the monomer which may produce irritation of the respiratory tract*, eyes, and possibly the liver. (emphasis added)

In 1986, after receiving reports of damage to soft contact lenses, Howmedica requested, and the FDA approved, an additional warning for the Simplex package insert referring to the vapors created during the mixing process as "noxious and irritating."

The FDA was deeply involved in drafting and editing the warnings on the Simplex label and package label, beginning with the product's approval in 1971 and continuing on through the period in which Brooks was exposed to it. Through its approval of the PMA application for Simplex and its continuing series of directives, the agency imposed specific federal requirements on Howmedica. The failure to warn claim Brooks seeks to assert could impose state requirements which conflict or interfere with these federal directives. Because those "particular state requirement[s] threaten[ ] to interfere with . . . specific federal interest[s]," *Lohr*, 518 U.S. at 500, Brooks' claim is preempted by the MDA.

D.

Brooks also argued in the district court that Simplex instructions were inadequate under federal law because FDA regulations require package labeling for prescription products to contain information about "any relevant hazards, contraindications, side effects, and precautions." 21 C.F.R. § 801.109(c) (2000). Brooks claims that her common law claim contains requirements identical to those imposed under federal law and is therefore not preempted. Brooks is correct in her assertion that a claim of failure to comply with FDA regulations is not preempted by the MDA, *Lohr*, 518 U.S. at 495, since such a state claim imposes no requirement "different from, or in addition to" any federal requirement. *Id.* at 496-97. *See also id.* at 513 (O'Connor, J., concurring in part and dissenting in part). Her assertion that she has put forward such a cause of action is a separate issue, however. The district court dismissed "any claim that Howmedica failed to comply with FDA rules or regulations" because it found no showing of noncompliance. The panel treated this claim as one for negligence per se unsupported in the record. Brooks asserts that her argument has been misunderstood and that she alleges a violation of state law that "parallels" similar requirements under federal law.

This unpled claim lacks both clarity and support, and we find no error in its dismissal. To the extent that Brooks attempts to distance herself from the categorization of this claim as one for negligence per se, the claim begins to sound very similar to the preempted failure to warn claim just discussed. *Cf. Papike*, 107 F.3d at 742-43 (denying a claim that general labeling regulations require warnings beyond those contained in specific FDA

requirements). Under the type of theory Brooks advances the general duty of C.F.R. 801.109(c) could trump even the most specific FDA labeling directive and § 360k of the MDA could be completely circumvented. Moreover, Brooks has presented no evidence that Howmedica violated federal regulations or refused to add warnings drafted by the FDA, changed FDA-approved labels failed to meet regular reporting requirements, failed to report a known hazard to the FDA, or failed to comply with federal law in any other respect. We conclude that this claim was properly dismissed on summary judgment.

V.

Simplex package labeling was subject to meticulous and ongoing federal regulation from the product's approval in 1971 through the time of Brooks' exposure to it. The FDA imposed specific federal requirements on Simplex through the PMA and NDA process. The specific state requirement Brooks seeks to establish by her common law claim would interfere with the specific federal requirements set for Simplex. Her claim is therefore preempted under § 360k of the MDA because it would impose a specific state requirement "different from, or in addition to" specific federal requirements. There is also no showing that Howmedica violated federal regulations. For these reasons, we affirm the judgment of the district court.

BYE, Circuit Judge, with whom HEANEY, Circuit Judge, joins, dissenting in part.

The majority stitches together a coherent, scholarly explication of § 360k preemption from the complicated

opinions of the Supreme Court in *Medtronic, Inc. v. Lohr*, 518 U.S. 495 (1996). I admire the majority's efforts. I also agree with its development of a three-step test, in which courts must discern the federal requirement imposed on a medical device manufacturer, then the state requirement imposed on that manufacturer, and finally compare the two to determine whether they present conflicting obligations. Though I agree with the standard expressed by the majority, I strongly disagree with its application of that standard to the facts of Carol Brooks's case and I respectfully dissent in that respect.

Following *Lohr*, we search for incompatibility between state laws (or putative state court judgments) and federal requirements imposed on manufacturers. Howmedica claims that the FDA's labeling requirements for Simplex conflict with a hypothetical adverse judgment on Brooks's state-law failure-to-warn claim. Howmedica raises two distinct arguments in support of this claim, but neither survives careful scrutiny. The majority adds two considerations in favor of preemption that I find unpersuasive. I address these four arguments in turn.

I

Howmedica professes that it is powerless to alter Simplex's packaging or warning insert, and hence it could not comply both with a state-law judgment and the federal labeling regulations. In effect, while a state-law judgment would require Howmedica to *add* to its labeling and package insert, it asserts, federal regulations would require Howmedica *not to add* to its labeling and package

insert. Howmedica submits that this Catch-22 epitomizes the need for, and importance of, § 360k preemption.

Howmedica's argument misstates a critical premise. FDA labeling regulations do not mandate that Simplex's label and package insert remain freeze-framed in their 1971-approved state. The FDA's regulations authorize Howmedica to initiate changes to Simplex's labeling. *See* 21 C.F.R. §§ 814.39(d)(2)(i) (authorizing medical device manufacturers to change labels to "add or strengthen a contraindication, warning, precaution, or information about an adverse reaction"), (d)(2)(ii) (permitting "[l]abeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device"). Section 814.39(d)(2) is not a moth-eaten relic of past regulatory efforts to which we attach little or no importance. The provision is a vital component of the FDA's larger regulatory mission of ensuring that manufacturers amend their warnings and their products in response to safety concerns and scientific advancements. The Supreme Court explicitly acknowledged the provision's importance in *Lohr:* "We also note that the agency permits manufacturers of devices that have received PMA to make certain labeling . . . changes which would enhance the safety of the device or the safety in the use of the device without prior FDA approval. *See* 21 CFR §§ 814.39(d)(1) and (2) (1995)." *Lohr,* 518 U.S. at 497 n.16 (punctuation removed).

If, for example, Howmedica learns that Simplex poses an unforeseen risk to consumers' health, Howmedica may immediately alter Simplex's labeling and package inserts to warn users of the newly-discovered risk. Howmedica does not have the final say, of course;

Howmedica has only the power to initiate review before the FDA concerning the merits of additional warnings. Interim warnings added by a manufacturer must be simultaneously submitted for FDA approval, and the proposed additions will be vetted by FDA doctors. If the FDA approves the additional warnings, the manufacturer may continue to display them. If the FDA rejects the additional warnings, however, the manufacturer must then remove the warnings to maintain compliance with the FDA's specific mandate. In sum, while FDA approval is pending, a manufacturer may include additional warnings on labeling and package inserts.

Section 814.39(d)(2) relieves any tension between Brooks's failure-to-warn claim and the FDA's ongoing oversight of Simplex labeling. Simplex's label and package insert have never contained warnings or information about the risk of contracting asthma. Brooks asserts that the scientific community began to learn of the asthma-inducing propensity of methyl methacrylate vapors in 1985 and 1986, more than a decade after the FDA approved Simplex for use in the United States. Brooks claims that Howmedica negligently failed to warn Simplex users that repeated exposure to vapors released in the mixing process could cause occupational asthma. Though the FDA approved Simplex's labeling without the type of asthma warnings suggested by Brooks, Howmedica could have sought FDA approval to add such warnings in the mid-1980s. Under § 814.39(d)(2), Howmedica could have altered its label or package insert – unilaterally – to alert users to the dangers of contracting asthma, pending permanent FDA approval of those warnings.

Had the FDA refused permission to add asthma warnings, Brooks's failure-to-warn claim would almost certainly be preempted. In that hypothetical instance, Howmedica would face the dilemma it so fears: a state law judgment would effectively require it to add an asthma warning that the FDA mandated must not be included. That hypothetical example is not the present case, however. In this case, Howmedica made no effort to warn Simplex users about asthma, though it had the power to do so initially, and could have done so permanently with the FDA's approval. Brooks's attempt to hold Howmedica liable for this alleged shortcoming in no way conflicts with FDA oversight of medical device labeling generally, or with Simplex's federal labeling requirements specifically.

My understanding of § 814.39(d)(2)'s role in the preemption analysis is identical to that of the former Chief Counsel of the FDA, Richard Cooper. "In some situations, FDA has not, at the relevant time, considered the precise question of whether the insert it had previously approved should be changed in light of subsequent information. Where that is the case, there would seem to be no relevant federal decision entitled to supremacy." Richard Cooper, *Drug Labeling and Products Liability: The Role of the Food and Drug Administration*, 41 Food Drug Cosm. L.J. 233, 234-35 (1986) (discussing the regulatory predecessor to § 814.39(d)(2)). Cooper cautions courts not to "overread" FDA regulations as permitting drug manufacturers *carte blanche* authority to change labeling or package inserts, *id.* at 235-36, a point with which I fully agree. But Cooper ultimately ascribes to the fundamental point we

raise above: manufacturers possess the authority, consistent with § 814.39(d)(2), to initiate the process of changing a medical device label to warn users of a newly-discovered risk. Manufacturers who negligently fail to seek FDA approval for such additional warnings (and to supplement their warnings pending FDA approval) cannot benefit from § 360k's preemption defense because they encounter no conflict between their respective state and federal obligations.

In the present case, Brooks's state law failure-to-warn claim and the FDA's scheme of regulatory oversight may coexist without impediment, and thus preemption is inappropriate.

II

Howmedica also argues there is actual conflict between state and federal requirements – even accepting my interpretation of § 814.39(d)(2) for argument's sake. Howmedica contends the FDA rejected the type of asthma warning that Brooks advocates when it approved Simplex's initial warnings in 1971, and when it oversaw Simplex labeling changes in 1975 and 1976. Howmedica asserts it presented possible warnings to the FDA that encompassed asthma-type risks. The FDA incorporated some of those warnings into the package insert, but rejected others. In either event, Howmedica posits, the FDA's decision to accept or reject such warnings constitutes specific federal regulations inconsistent with Brooks's effort to obtain a state-law judgment requiring an asthma warning.

The record does not substantiate Howmedica's assertions. In the first place, Howmedica has not directed the court to *any* evidence that warnings specifically pertaining to asthma were discussed by the FDA or presented for its consideration. Howmedica is therefore left to contend that the warnings it did propose, and those considered by the FDA, encompass the same territory as an asthma warning. Howmedica argues, in effect, that some of the warnings it proposed would have "done the work" of an asthma warning, and thus the FDA's rejection of those warnings implies a specific federal prohibition. This contention also lacks any basis for support in the record presented to the district court.

The package insert warnings drafted by the FDA in 1971 during the PMA process mention the following:

> Caution should be exercised during the mixing of [Simplex's] two components to prevent excessive exposure to the concentrated vapors of the monomer which may produce irritation of the respiratory tract, eyes, and possibly the liver.

Brooks App. 202 (Aff. of Christopher Lawler, Exh. K) (Dec. 15, 1998).

It is obvious this warning does not encompass asthma in the manner Howmedica suggests. Warning a Simplex user of possible "irritation of the respiratory tract" is not equivalent to warning the user about contracting asthma through repeated exposure. The warning does not adequately reflect the medical reality of an asthmatic condition. Asthma is a chronic disease that derives from repeated exposure to irritants or allergens, *see* 1 Gale Encyclopedia of Medicine 347 (1999); Brooks

App. 409 (Depo. of Dr. Kaye) (Dec. 16, 1998), yet the Simplex warning bears no mention of duration or long-term exposure. To the contrary, the warning implies to the reader that possible irritation will be only temporary. Moreover, the label does not even hint that such exposure might cause disease.

Howmedica's argument fares no better if the warning in fact connotes permanent harm. Viewed most charitably to Howmedica, the warning's reference to "irritation of the respiratory tract" might incorporate the possibility of long-term suffering. Brooks strongly disagrees any such inference may be drawn, and thus a dispute of material fact (perhaps a dispute of medical fact) would prevent the entry of summary judgment. Because we are presently reviewing the propriety of summary judgment entered *against* Brooks, we are in no position to draw factual inferences in favor of Howmedica. If such a factual dispute exists, its resolution – and thus the overarching preemption question presented in this case – would require some initial fact-finding. *Cf. Brown v. Hotel & Rest. Employees & Bartenders Int'l Union*, 468 U.S. 491, 511 (1984) (expressing an inability to resolve a preemption question until appropriate findings of fact had been made to permit review of the legal question).

Howmedica's assertion that the FDA considered and rejected warnings encompassing asthma in 1975 and 1976 is even less believable. In early 1975, the FDA commenced review of the inhalation toxicity of methyl methacrylate vapors. Howmedica and other manufacturers were required to participate in committee meetings and other proceedings with the FDA. As a result of these discussions, the FDA required Howmedica to alter the

Simplex package insert to state Simplex's liquid component was highly flammable and operating rooms should be adequately ventilated. *See* Brooks App. 126 (Lawler Aff. ¶ 40). The FDA also required Howmedica to send a "Dear Doctor" letter pertaining to concerns of inhalation toxicity. *See id.* at 325-26 (Lawler Aff., Exh. Z).

It cannot fairly be contended that the warnings the FDA required in the mid-1970s were germane to asthma. The FDA was then concerned with the inhalation toxicity of methyl methacrylate vapors. Toxins are essentially poisons. *See supra,* Gale Encyclopedia at 2878. But Brooks does not claim she was *poisoned* by exposure to Simplex. She claims she contracted *asthma* from repeated exposure to the vaporous byproducts of the Simplex mixing process. Howmedica has not directed our attention to any evidence that suggests the FDA considered and rejected warnings that would have notified Simplex users of the risk of contracting asthma. The FDA's consideration of inhalation toxicity studies simply does not indicate the FDA considered warnings related to asthma.

And even if the FDA *had* considered and rejected asthma warnings in the 1970s, Howmedica's counterargument would still fail. Brooks's failure-to-warn claim is predicated upon scientific discoveries of the mid-1980s. *See, e.g.,* Brooks App. 78 (Plaintiff's Memo. Opp. Summ. J. 21) (Jan. 8, 1998) ("In 1985, scientific literature established a causal relationship between the induction of occupational asthma and exposure to methyl methacrylate, a component of Defendants' bone cement."); *id.* at 465 n.4 (Expert report of Environmental Health & Safety, Inc.) (July 15, 1998) (citing S. Lozewicz et al., *Occupational Asthma Due to Methyl Methacrylate and Cyanoacrylates,* 40

Thorax 836 (1985)); *id.* at 480. FDA regulations require manufacturers to apprize themselves and the agency of new product risks that come to light subsequent to market approval. Howmedica could have sought FDA approval (under § 814.39(d)(2)) to add asthma warnings when scientists began to notice (or at least thought they began to notice) a causal link between methyl methacrylate vapor exposure and occupational asthma in the mid-1980s. Howmedica could have added such warnings to its package insert immediately, pending final FDA approval or rejection. Howmedica's reference to FDA actions in the 1970s is not responsive to Brooks's assertion that Howmedica failed to warn Simplex users of the risk of contracting asthma when such risks became known in 1985.

Howmedica's argument therefore fails. No evidence in the record demonstrates that current Simplex labeling warns users of the possibility of contracting asthma. Nor does any evidence suggest the FDA considered and rejected other warnings that might have encompassed asthma within their scope. The FDA has not issued Howmedica any specific federal directive pertinent to asthma, and consequently, Howmedica's claim of preemption based upon conflicting state and federal requirements melts away. The majority therefore errs in holding that Brooks's failure-to-warn claim is preempted by federal law.

III

In places, the majority seems to suggest that even if Howmedica's state and federal requirements do not conflict, Brooks's hypothetical state-law judgment nevertheless "threatens to interfere with a specific federal interest," *ante* at 14 (quoting *Lohr*, 518 U.S. at 500), and thus her state-law claim should be preempted. *See ante* at 19 ("Such 'threaten[ed] interfere[nce]' between specific requirements of state and federal law requires preemption under the MDA.") (quoting *Lohr*, 518 U.S. at 500). I find this suggestion contrary to *Lohr* and legally untenable in any event.

While predicting that § 360k and its concomitant regulations will occasionally preempt state tort claims, *Lohr* states "it is impossible to ignore [the regime's] overarching concern that preemption occur only where a particular state requirement threatens to interfere with a specific federal interest." 518 U.S. at 500. After uttering this broad platitude, the Court got down to the business of deciding *when* a specific federal interest might be threatened. The ensuing paragraph considers the sort of state and federal requirements imposed on medical device manufacturers. And then, to sum up, the Court concludes "[t]he statute and regulations, therefore, require a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations." *Id.*

The Court's language, and the structure of its discussion, emphasize that while the *overarching concern* of

§ 360k preemption is to prevent "threatened interference" with "federal interests," the *standard* by which to determine such a threat is actual conflict between state and federal requirements. In this case, there is no actual conflict between Howmedica's federal labeling requirements and the requirements imposed by a hypothetical state-law judgment for Brooks – as I have demonstrated above. It would be odd, to say the least, to discard the Court's analytical framework of conflict-motivated preemption in favor of the generic concern present in any preemption case that federal interests persevere.

It is critical to distinguish between the threat to federal interests, to which *Lohr* alludes, and the threat to a particular manufacturer, which *Lohr* does not similarly discuss. The federal interest in MDA cases will rarely if ever be threatened. The FDA always has the last word in labeling decisions. If a manufacturer presents a § 841.39 request to the FDA to add a warning, the FDA's ruling on that request will have preemptive effect. If the FDA refuses permission to add the warning, a subsequent state-law tort claim based on the failure to include that warning will be preempted. The federal interest – the FDA's regulatory mission – is never compromised by a competing state-law judgment because the FDA's decision supplants state tort law.

I acknowledge that manufacturers who are sued in tort before they request additional warnings from the FDA may be threatened. But the federal interest – the subject of discussion in *Lohr* – will not be threatened. Suppose a plaintiff prevails on a state-law failure-to-warn claim against a medical device manufacturer. After judgment is entered, the manufacturer seeks FDA approval to

add the warning compelled by the state-law judgment. If the FDA refuses to approve that warning, the manufacturer need not place the warning on its labels because the FDA's requirement preempts the effect of the state-law judgment. In this scenario, the manufacturer may have lost considerable time and money defending the suit, and thus its interests have in some sense been threatened. But the *federal* interest has not been threatened. When the FDA was presented with a label modification request, the FDA rejected it, and the FDA's judgment carries the day and supplants the state-law judgment for the future based upon § 360k preemption. Section 360k preemption, as envisioned by the Supreme Court, could hardly protect the federal interest more capably.

I therefore resist the majority's apparent attempt to resolve this case based on generic concerns that federal interests might be "threatened."

IV

Finally, spurred on by *amicus curiae*, the majority makes passing reference to certain policy considerations that militate against a preemption holding in this case. The majority argues that Brooks's effort to add another warning to Simplee's label could result in "over-warning" consumers. The majority also posits that Brooks's lawsuit should not establish medical device labeling policy because she lacks the FDA's capacity to appreciate and balance all the risks presented.

These arguments suggest the FDA's regulations and directives should always supplant state tort suits. Yet the Supreme Court implicitly rejected these policy arguments

in *Lohr* by holding at least one plaintiff's state-law failure-to-warn claim was not preempted under § 360k.

Moreover, the majority's considerations form an inappropriate basis for resolving an express preemption case. When Congress has declared its preemptive intent in statutory form, we are limited to interpreting its language in discerning the scope of federal preemption. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992) (declaring that the preemptive scope of the Federal Cigarette Labeling and Advertising Act is "governed entirely" by the language in its express preemption provision, 15 U.S.C. § 1334(b)). In the MDA, Congress set forth its intention to preempt some state regulations and requirements placed on medical device manufacturers. Reasonable jurists may debate the meaning of § 360k's words as they apply to particular cases. But we may not rely on broader considerations of public policy, for then we overstep our duty faithfully to interpret the language upon which Congress has agreed.

I respectfully dissent in part, though I do join in Part IV.D of the majority opinion, which concludes that the district court properly granted summary judgment as to Brooks's seeming negligence per se claim.

A true copy.

ATTEST:

CLERK, U.S. COURT OF APPEALS, EIGHTH CIRCUIT.

United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 00-1188

Carol Jean Brooks, Appellant,	*	
St. Luke's Hospital, Intervenor below,	*	Appeal from the United States District Court for the District of Minnesota
v.	*	
Howmedica, Inc., a Delaware Corporation, Division of Pfizer Hospital Products Group, Inc.; Pfizer, Inc.; Howmedica International, Ltd., Appellees.	*	[PUBLISHED]

Submitted: October 18, 2000
Filed: January 10, 2001

Before MURPHY, HEANEY, and BYE, Circuit Judges.

BYE, Circuit Judge.

This appeal requires us to assess the preemptive power of the Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539 (codified in

various sections of 21 U.S.C. and 26 U.S.C.), in view of the Supreme Court's recent decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

BACKGROUND

In the late 1960s, defendants Howmedica, Inc., Pfizer, Inc. and Howmedica International, Ltd. (together, "Howmedica") developed a product called "surgical Simplex® P Radiopaque bone cement" ("Simplex"). Surgeons employ Simplex in a variety of orthopedic procedures, including joint, hip, knee, shoulder and elbow replacement surgeries, and the repair of bone fractures.

Simplex consists of two components: a colorless liquid and a powder. Prior to surgery, the liquid and powder ingredients are mixed together, forming an amorphous mass. That mass quickly hardens into a cement-like substance that bonds tissues and bones. The mixing process releases a potentially harmful chemical byproduct, methyl methacrylate vapors. Nurses and surgical technicians who mix the Simplex components often inhale those methyl methacrylate vapors.

Howmedica submitted Simplex to the Food and Drug Administration (FDA) for marketing approval on February 8, 1971. Howmedica provided the FDA with a wealth of safety information concerning Simplex: details of animal studies; manufacturing and quality control procedures; identification of possible side effects; results of clinical trials; summaries of surgical cases and post-operative complications; long-term carcinogenicity and toxicity studies; and the results of investigational use by 67

physicians in 1508 hip replacements involving 2800 preparations of the bone-cement.

The FDA subjected Simplex to the New Drug Application (NDA) process. As part of the NDA process, the FDA scrutinized Howmedica's proposed labeling and packaging for Simplex. The FDA reviewed, and in many instances rewrote, language to be included on Simplex's package (and its insert) explaining how to use the bone cement. FDA doctors met with Howmedica representatives on several occasions to discuss the content of Simplex's label and inserts. The FDA also informed Howmedica that Simplex would not be approved until the FDA had seen the actual printed labels and the final Simplex package insert. Each Simplex label, and every word included in the package insert, was scrutinized by FDA doctors and representatives.

The FDA formally approved Simplex for marketing on October 7, 1971. In subsequent years, the FDA required modifications to Simplex's labels and package inserts. In 1973, in response to a rat-study, the FDA recommended revising the warning section of the label; Howmedica revised the label accordingly. In 1976, doctors released a study observing operating room personnel's response to Simplex. In response to that study, the FDA required Howmedica to send out a "Dear Doctor" letter, cautioning physicians to use Simplex carefully, and referring doctors to the package insert warnings.

In 1965, Carol Brooks began work as a licensed practical nurse in Duluth, Minnesota. Between 1978 and 1981, she worked at St. Mary's Hospital in Duluth. At St. Mary's, Brooks regularly mixed bone cement for use in

surgical procedures. In late 1983, Brooks left St. Mary's and joined the staff at St. Luke's Hospital in Duluth.

Brooks worked almost exclusively in the orthopedic surgery department at St. Luke's. During her first year on the job, she mixed bone cement for an average of four cases per week. Brooks's bone cement mixing duties increased steadily thereafter. In 1992, she assisted surgeons in approximately 10 operations per week requiring the use of bone cement. In virtually all such operations, Brooks mixed the bone cement herself, or she was positioned nearby as another nurse mixed the cement.

In 1989, Brooks began to cough frequently at work. Her persistent cough worsened and, in 1991, she was diagnosed with asthma. Brooks's doctor attempted to find the cause of her asthma, but he could not pin down its precise etiology. Brooks's doctor even phoned Howmedica to inquire about Simplex's components. Though the doctor was unable to conclude that Simplex was the cause of Brooks's asthma, he restricted her exposure to Simplex at work. In 1992, Brooks suffered an acute asthma attack at work, and was thereafter restricted from exposure to Simplex. Brooks left work in 1995, unable to do her job. She has been diagnosed with occupational asthma. Her doctors now attribute its cause to her repeated exposure to methyl methacrylate vapors, a Simplex byproduct.

On March 19, 1997, after her illness prevented her from working, Brooks commenced a products liability action against Howmedica. In particular, Brooks contended that Howmedica had negligently failed to warn her of the danger of contracting occupational asthma by

inhaling methyl methacrylate vapors during the process of mixing the liquid and powder components of Simplex. In addition, Brooks claimed that Howmedica failed to comply with FDA labeling regulations. After more than a year of discovery, Howmedica moved for summary judgment. Both sides filed affidavits, many of which explained the medical and technical issues in the case. The district court ultimately granted Howmedica's motion, and entered judgment adverse to Brooks. Brooks now appeals from that judgment.

DISCUSSION

We review de novo a district court's grant of summary judgment by applying the same standard as the district court. *See Treanor v. MCI Telecomm. Corp.*, 200 F.3d 570, 573 (8th Cir. 2000). Summary judgment is appropriate when the evidence – viewed in the light most favorable to the nonmoving party – demonstrates that there are no disputed issues of material fact and the moving party is entitled to judgment as a matter of law. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986).

A. Brooks's Failure-to-Warn Claim

Brooks alleged that Howmedica failed to warn her of the risk of contracting asthma through repeated exposure to methyl methacrylate vapors. The district court ruled that Howmedica was entitled to summary judgment because Brooks's state-law failure-to-warn claim was preempted by federal law. We reverse.

The MDA contains an express preemption provision that governs federal preemption of state law with respect to medical devices:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The Supreme Court recently analyzed the meaning and scope of § 360k preemption in *Lohr*. The plaintiff in *Lohr* suffered a complete heart block that required emergency surgery after her Medtronic pacemaker failed. She filed suit against Medtronic alleging products liability causes of action stemming from the failure of the company's Model 4011 pacemaker lead. After considering the nature and scope of § 360k preemption, the Supreme Court held that none of Lohr's Florida law causes of action were preempted.

Lohr clarified several aspects of § 360k preemption, but the Court's fractured holding has troubled the lower federal courts. *See, e.g., Kemp v. Medtronic, Inc.*, 231 F.3d 216, 224 (6th Cir. Nov. 1, 2000) ("The various courts of appeals that have confronted issues of preemption arising

under the MDA have struggled mightily with *Lohr*'s language in the effort to discern its holding."). Justice Stevens favored very narrow preemption; he wrote a plurality opinion for four Justices. *See Lohr*, 518 U.S. at 474-503 (Stevens, J., joined by Kennedy, Souter and Ginsburg, JJ.). Justice O'Connor favored far broader federal preemption, and wrote a partial concurrence and partial dissent for four Justices. *See id.* at 509-14 (O'Connor, J., joined by the Chief Justice, and Scalia and Thomas, JJ.). Justice Breyer agreed with portions of both opinions, and with Justice Stevens's overall result, but wrote a separate opinion. *See id.* at 503-508 (Breyer, J.). From this, then, we must divine the Supreme Court's intentions.

All nine Justices agreed that § 360k's reference to state "requirements" included common law tort actions. *See Lohr*, 518 U.S. at 486-91 (Stevens, J.), 504-505 (Breyer, J.), 510 (O'Connor, J.). Justices Stevens and Breyer then parted company from Justice O'Connor's foursome. Justices Stevens and Breyer argued that courts' interpretation of § 360k should be "informed by" the FDA's own regulations explaining § 360k. *See id.* at 495-97 (Stevens, J.), 505-507 (Breyer, J.). Justice O'Connor bitterly dissented from the Court's decision to look to the FDA's preemption regulations for guidance. *See id.* at 509 (O'Connor, J.) (decrying the decision as "bewildering and seemingly without guiding principle"). Notwithstanding Justice O'Connor's opinion for four Justices, however, a

majority[1] of the Court sought assistance from FDA regulations in interpreting § 360k's preemptive force.

The FDA preemption regulation provides that "state requirements are pre-empted 'only' when the FDA has established 'specific counterpart regulations or . . . other specific requirements applicable to a particular device.' " *Id.* at 498 (quoting 21 C.F.R. § 808.1(d)). The FDA regulation also states that § 360k "is not intended to pre-empt 'State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices . . . or to unfair trade practices in which the requirements are not limited to devices.' " *Id.* at 499 (quoting 21 C.F.R. § 808.1(d)).

Justice Stevens – joined by Justice Breyer in this portion of the plurality opinion – proceeded to interpret § 360k in view of that FDA preemption regulation. Justice Stevens's analysis divided the overarching preemption question into three distinct steps. Each step focused on a separate aspect of the preemption analysis: the state requirement, the federal requirement, and a thoroughgoing comparison of the two requirements. *See Lohr*, 518 U.S. at 500.

Preemption analysis begins with an examination of the putative state "requirement" described in § 360k(a). Only state laws specific to the medical device in question, or general state laws that have "the effect of establishing a substantive requirement for a specific device," *Lohr*, 518

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[1] *Cf. Vasquez v. Hillery*, 474 U.S. 254, 261 n.4 (1986) (explaining that the amalgamated view of five Justices forms the holding of the Court).

U.S. at 500, may be preempted. Whether the state law is specific or general, the state law must relate to the safety or effectiveness of the device. *See* 21 U.S.C. § 360k(a)(2).

Second, a specific federal requirement must govern the medical device at issue. "[F]ederal requirements must be 'applicable to the device' in question, and, according to the regulations, pre-empt state law only if they are 'specific counterpart regulations' or 'specific' to a 'particular device.' " *Lohr*, 518 U.S. at 500.

Third, if both such state and federal requirements exist, they must be compared using traditional principles of conflict[2] preemption. This comparison is the heart of the analytical framework. If state and federal laws render a medical device manufacturer's compliance with both impossible, then federal law preempts state law. *See id.* at

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[2] Although conflict preemption principles loom large in the Court's analysis, *field* preemption does not animate § 360k preemption analysis. Five Justices concluded that Congress did not create an exhaustive or pervasive scheme of federal regulation that would supplant state tort law altogether. *See Lohr*, 518 U.S. at 491 (Stevens, J.) ("There is, to the best of our knowledge, nothing in the hearings, the Committee Reports, or the debates suggesting that any proponent of the [MDA] legislation intended a sweeping pre-emption of traditional common-law remedies against manufacturers and distributors of defective devices."), 508 (Breyer, J.) ("I can find no . . . indication that either Congress or the FDA intended the relevant FDA regulations to occupy entirely any relevant field."). Justice O'Connor's opinion, in contrast, would have held that the FDA's extensive labeling requirements occupied the field, thereby preempting failure-to-warn claims and other common law claims, but Justice O'Connor failed to command the vote of five Justices on this point. *See id.* at 514 (O'Connor, J.).

501 (Stevens, J.) (explaining that § 360k "protects" specific federal regulations from interference by potentially contradictory state requirements), 507-508 (Breyer, J.). In addition, if state law necessarily impedes the fulfillment of Congressional objectives, federal law preempts state law. *See id.* at 501 (Stevens, J.) (explaining that most general common law claims would not "impede the ability of federal regulators to implement and enforce specific federal requirements"), 507-508 (Breyer, J.).

> The statute and regulations, therefore, require a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations.

Id. at 500 (Stevens, J.).

With this tripartite scheme in mind, we turn our attention to the respective state and federal laws, and their compatibility.

1. State Requirement

Brooks claimed that Howmedica failed to warn her of the dangers of exposure to methyl methacrylate vapors while mixing Simplex. Brooks argues that a common law failure-to-warn claim is generic, and therefore cannot constitute a "specific" state requirement subject to federal preemption.

We agree with Brooks that Minnesota failure-to-warn claims are generic in the sense that such claims apply to a wide range of products. *Cf., e.g., Kallio v. Ford Motor Co.,*

407 N.W.2d 92, 99-100 (Minn. 1987) (motor vehicle); *Germann v. F.L. Smithe Machine Co.*, 395 N.W.2d 922, 924-25 (Minn. 1986) (hydraulic press); *Frey v. Montgomery Ward & Co., Inc.*, 258 N.W.2d 782, 787-88 (Minn. 1977) (space heater); *Marcon v. Kmart Corp.*, 573 N.W.2d 728, 730-32 (Minn. Ct. App. 1998) (plastic snow sled). But this conclusion doesn't resolve the more difficult question framed in *Lohr:* may an otherwise generic common law claim act as a device-specific requirement by virtue of the claim's application to a particular product?

Five Justices in *Lohr* indicated that generic common law claims could be preempted, though such claims aren't device-specific in the abstract. Those Justices (through the opinions of Breyer and O'Connor, JJ.) concluded that, in application, a common law judgment adverse to a medical device manufacturer would force compliance in much the same fashion as a state's enactment of regulations or other positive law specific to the medical device at issue. Justice Breyer stated that "insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action." *Lohr*, 518 U.S. at 504-505 (Breyer, J.). Justice O'Connor's partial concurrence echoed Justice Breyer's sentiment that common law tort actions frequently act as state "requirements," as described in § 360k. *See id.* at 510-11 (O'Connor, J.); *see also id.* at 500 (Stevens, J.) (allowing for the remote possibility that general state requirements could sometimes be preempted).

A judgment favoring Brooks would provide precisely the sort of specific state-law mandate, or requirement, envisioned by Justices Breyer and O'Connor. If a jury found Howmedica liable for failing to warn Brooks and others of Simplex's asthma-inducing propensity, then the resulting judgment against Howmedica would effectively require Simplex to bear more expansive labeling detailing the risk of contracting asthma from exposure to chemical byproducts in the mixing process. Thus we find that Brooks's state law failure-to-warn claim would have the effect of a specific state law requirement, the first step in the preemption triad.

2. Federal Requirement

We turn now to the second stage of the analysis, the specific federal requirement. We have previously held that the premarket approval (PMA) process to which new medical devices are subjected "is a specific [federal] requirement for a device within the meaning of 21 U.S.C. § 360k(a) and 21 C.F.R. § 808.1(d)." *Martello v. Ciba Vision Corp.*, 42 F.3d 1167, 1169 (8th Cir. 1994) (citations omitted). Although *Martello* was decided before *Lohr*, we are confident that *Martello*'s holding survives *Lohr*, at least in this respect. *Lohr* did not address the preemptive power of the PMA process; instead, *Lohr* focused on a different (and far less stringent) approval process, the substantial equivalence, or § 510(k) process. *See Lohr*, 518 U.S. at 480. *Lohr*'s conclusion that *less* rigorous federal review doesn't preempt state common law claims fails to resolve whether *more* rigorous federal review would preempt a state common law claim – the question we face.

The Supreme Court of Rhode Island, facing the same situation, answered the question in terms that apply equally well in this case.

> We think rather than expressing entirely generic concerns of safety, the FDA has expressed explicit concerns toward [Simplex]. We conclude that the premarket approval process constitutes a specific federal interest as contemplated in *Medtronic [v. Lohr]* and that, therefore, the FDA approval served to impose strict FDA [warning and labeling] requirements upon the defendant.

Fry v. Allergan Medical Optics, 695 A.2d 511, 516 (R.I. 1997).

Our conclusion is buttressed by the considered views of the Sixth and Seventh Circuits, both of whom have recently explained that the PMA process may be considered specific federal regulation. *See Kemp*, 221 F.3d at 225-28 (dictum); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997) ("[T]he PMA process . . . can constitute the sort of specific federal regulation of a product that can have preemptive effect."); *but see Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1378-77 (11th Cir. 1999) (concluding that the PMA process is "conceptually distinct" from specific federal regulation of medical devices).

Of course, Simplex was not actually reviewed under the PMA process. When Howmedica developed Simplex in the late 1960s, and submitted Simplex to the FDA in 1971, PMA review had not yet been instituted by the FDA. But the FDA *did* test and review Simplex under the older New Drug Application (NDA) process, the precursor to the FDA's post-1976 PMA process.

As part of the NDA process, the FDA scrutinized Howmedica's proposed labeling and packaging for Simplex. The FDA reviewed and recrafted language that appeared on Simplex's package and package insert. FDA doctors also met with Howmedica representatives to discuss the content of Simplex's labels and warning inserts. Prior to Simplex's release into the market, the FDA reviewed each label, and every word, included in Simplex's package label and package insert. This federal review process constitutes "specific" regulation; the full might of the FDA's regulatory power was brought to bear upon a single product, Howmedica's Simplex.

Although the PMA process is arguably more rigorous than the older NDA process, the purpose of both processes is identical: to ensure that medical devices are reviewed for safety in advance of their release into the marketplace. As Howmedica points out, PMA is the functional equivalent of the old NDA approval process. Consequently, a medical device subject to NDA review ought to receive the same protection afforded a PMA-reviewed device.

Brooks disputes the fact that the PMA and NDA processes are functional equivalents. But even if we assumed the truth of Brooks's contention – something we are disinclined to do – Simplex is deemed to have been PMA-approved by operation of law. *See* 21 U.S.C. §§ 360e(b)(1)(A), 360j(*l*)(3)(A); 21 C.F.R. § 888.3027 (establishing, in combination, that drugs reclassified as devices in 1976 – such as Simplex – are considered PMA-compliant). As a result, we are not persuaded by Brooks's argument.

As we explained above, *Martello* holds that a PMA-compliant medical device has been subjected to specific federal regulation. Because Simplex was subjected to a PMA-equivalent approval process (NDA), and because Simplex is deemed "PMA-compliant" by virtue of federal regulations, *Martello* applies. Simplex was subject to specific federal regulation.

3. Comparing Federal and State Requirements

Having established the existence of pertinent state and federal requirements, we must now compare those requirements. Following the Supreme Court's lead, we search for (1) outright incompatibility between the state and federal requirements, or for (2) state laws that defeat the purpose of federal law or Congressional intent. Justice Stevens's comparison between the *Lohr* plaintiff's common law claims and applicable federal requirements focused on both these paths to preemption. *See Lohr*, 518 U.S. at 501.

Justice Stevens suggested that state regulations that complement federal regulations, i.e., those that peacefully coexist without imposing conflicting duties upon manufacturers, would not yield to § 360k's preemptive reach. Justice Stevens analogized complementary state requirements to "local fire prevention regulations" and to "zoning codes," neither of which requires manufacturers to avoid compliance with federal health requirements enunciated in the MDA. *See id.* at 501-502.

In addition, state requirements that duplicate federal requirements pose no threat to federal law, and thus will not be preempted. Only state requirements that *differ*

from federal law, *see* 21 U.S.C. § 360k(a)(1), and those that are *divergent* from federal law, *see* 21 C.F.R. § 808.1(d), require preemption. *See Lohr*, 518 U.S. at 496-97 (Stevens, J., joined by Breyer, J.) ("The regulations promulgated by the FDA expressly support the conclusion that § 360k 'does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.' ") (quoting 21 C.F.R. § 808.1(d)(2)); *id.* at 513 (O'Connor, J.) ("Section 360k does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*.") (italics in original). Thus a state law that provides a remedy for violation of FDA regulations, for example, doesn't impose a burden on manufacturers that is "different from" federal law. *See Lohr*, 518 U.S. at 495.

Howmedica argues that the FDA's labeling requirements for Simplex are inconsistent with a hypothetical adverse judgment on Brooks's state-law failure-to-warn claim. Howmedica professes that it is powerless to alter Simplex's packaging or warning insert, and hence it couldn't comply with both a state-law judgment and the federal labeling regulations. In effect, while the state-law judgment would require Howmedica to *add* to its labeling and package insert, it asserts, federal regulations would require Howmedica *not to add* to its labeling and package insert. Howmedica submits that this Catch-22 epitomizes the need for, and importance of, § 360k preemption.

Howmedica's argument suffers from a fatal defect: the argument misstates a critical premise. FDA regulations do not in fact mandate that Simplex's labeling and package inserts remain frozen in their 1971-approved

state. The regulations require only that Howmedica provide no less information and warning than the 1971-approved labeling. Howmedica is free to provide more information, and more detailed warnings, to consumers. *See* 21 C.F.R. §§ 814.39(d)(2)(i) (authorizing medical device manufacturers to change labels to "add or strengthen a contraindication, warning, precaution, or information about an adverse reaction"), (d)(2)(ii) (permitting "[l]abeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device").

Howmedica's assertion that the 1971 labeling on Simplex is set in stone by virtue of FDA regulations is wrong. *See Lohr*, 518 U.S. at 497 n.16; *Connelly v. Iolab Corp.*, 927 S.W.2d 848, 854 (Mo. 1996) ("Nothing in [the FDA] regulations prohibits Iolab from adding a warning to the label regarding unreasonably high complication rates."). An adverse judgment on Brooks's failure-to-warn claim would not, as Howmedica posits, force Howmedica to choose between complying with FDA regulations and the state law judgment. Nothing prohibits Howmedica from increasing the warnings and information it provides to consumers and health practitioners on Simplex's package and package insert.

Likewise, a judgment adverse to Howmedica on Brooks's failure-to-warn claim wouldn't interfere with Congressional intent or FDA policy. The FDA's *raison d'etre* is to review new medical devices to ensure that the devices are moderately safe before they are released into the marketplace. We struggle to imagine how a common law judgment requiring greater warnings would interfere with that purpose. Brooks's counsel captured the essence

of this point when he remarked at oral argument that "FDA regulations create floors, not ceilings." A common law judgment against a manufacturer such as Howmedica would raise the floor, not puncture the ceiling.

Because Howmedica could have added language warning consumers of asthma risks associated with exposure to Simplex without running afoul of federal requirements, Howmedica doesn't face a Catch-22. Howmedica could comply with both an adverse state-law judgment and FDA regulations. Accordingly, preemption is inappropriate in this instance. The district court erred in granting Howmedica's motion for summary judgment on Brooks's failure-to-warn claim.

At first blush, there appears to be tension between our holding and the language of § 360k. We hold that § 360k does not preempt a failure-to-warn action that might, if successful, require Howmedica to *add to* Simplex's warnings. Section 360k forbids state requirements that are "different from, or in *addition to*" federal law. 21 U.S.C. § 360k(a)(1) (emphasis added). The apparent tension is illusory, however, because (as the Supreme Court explained in *Lohr*) § 360k doesn't really mean what it says.

Justice Breyer demonstrated the folly of reading § 360k's "different from, or in addition to" language literally: every state requirement would then be preempted because, in some small or obscure way, every such state requirement could be deemed different or additive. *See Lohr*, 518 U.S. at 505 (Breyer, J.) ("Congress must have intended that courts look elsewhere for help [i.e., beyond the words in § 360k] as to just which federal

requirements pre-empt just which state requirements, as well as just how they might do so."). Justice Breyer sought refuge in "basic pre-emption principles," *id.* at 508, the twin notions of conflict and field preemption, *see id.* at 508-509. Justice Stevens likewise acknowledged the importance of conflict preemption analysis as a reprieve from § 360k's ambiguity. *See id.* at 503 (Stevens, J.).

The best illustration of Justices Stevens and Breyer's reliance upon conflict preemption to the exclusion of § 360k's very language comes from Justice O'Connor's separate opinion. Justice O'Connor dissented precisely on this point; she would have interpreted § 360k literally, as preempting each and every state law "different from, or in addition to" federal law.

> If § 360k's language is given its ordinary meaning, it clearly pre-empts any state common-law action that would impose a requirement different from, or in addition to, that applicable under the FDCA – just as it would pre-empt a state statute or regulation that had that effect. . . .
>
> The plurality's reasons for departing from this reading are neither clear nor persuasive. . . . The Court holds that an FDCA "requirement" triggers pre-emption only when a conflict exists between a specific state requirement and a specific FDCA requirement applicable to the particular device.

Lohr, 518 U.S. at 511.

Under Justice O'Connor's view, Brooks's failure-to-warn claim would certainly be preempted as an "additional" state requirement. But Justice O'Connor failed to garner four additional votes for her position. Thus her

opinion demonstrates, by negative implication, that five other Justices interpreted § 360k's ambiguous language to require conflict preemption analysis. The conflict preemption analysis we undertook with respect to Brooks's case reveals no tension between her failure-to-warn claim and FDA labeling requirements.

B. Failure to comply with FDA regulations claim

Sometime after the pleadings were filed, Brooks began to assert that Howmedica had violated, or had failed to comply with, FDA regulations. We are mindful of our liberal pleading rules, *see, e.g.*, Fed. R. Civ. P. 8(a)(2), (e)(1), as well as the Supreme Court's acknowledgment in *Lohr* that such claims often arise late in the life of a products liability action, *see Lohr*, 518 U.S. at 494-95. As a result, we construe Brooks's complaint to raise a "negligence per se" claim based upon Howmedica's alleged violation of FDA regulations. *Lohr* makes clear that this type of state-law claim against a medical device manufacturer would not be preempted. *See id.* at 495-96. Howmedica concedes as much.

Minnesota law recognizes a common law action for negligence per se stemming from a defendant's violation of FDA regulations. *See Femrite v. Abbott Northwestern Hosp.*, 568 N.W.2d 535, 539 & n.4 (Minn. Ct. App.1997). *Femrite* requires a plaintiff, such as Brooks, to prove both that she "belongs to the class of persons that the regulation is intended to protect," *id.* at 539, and that the defendant in fact violated the applicable FDA regulations, *see id.* at 542. The latter question is one of law, appropriate for disposition on summary judgment. *See id.*

("Considering these FDA documents, and the record as a whole, we conclude as a matter of law that the physicians' implantation of the screw devices in appellants' surgeries was a permissible 'off-label' use not in violation of FDA regulations."); *cf. Bammerlin v. Navistar Int'l Transp. Corp.*, 30 F.3d 898, 900 (7th Cir. 1994) ("The meaning of federal regulations is not a question of fact, to be resolved by the jury after a battle of experts. It is a question of law, to be resolved by the court.") (citations omitted).

We have no doubt that Brooks belongs to the class of persons whom the FDA intends to protect by promulgating labeling regulations. Brooks, like many nurses and surgical technicians, was regularly exposed to Simplex and its concomitant chemical byproducts. FDA labeling regulations are designed to promote safe and effective use of medical devices such as bone-cement. Howmedica cannot seriously contest Brooks's membership in the protected class.

Despite proving membership in the protected class, however, Brooks's claim founders on the second element – violation of FDA regulations. As we explained above, Howmedica fully complied with the FDA's labeling requirements at the time that Simplex was approved for use in 1971. In the intervening years, Howmedica altered Simplex's package and package insert to accommodate changes recommended by the FDA. As Howmedica indicated in its briefs, every word on the Simplex package and package insert has been formally approved by the FDA. It is folly to suggest, therefore, that Howmedica violated FDA regulations in labeling Simplex. As the district court pointed out, Brooks neglected to develop

any support in the record (or in her argument) that Howmedica violated FDA regulations.[3] We have scoured the record and the pertinent case law independently and located no additional support for Brooks's claim.

Because Brooks has not demonstrated any violation of FDA labeling requirements, her Minnesota-law negligence per se claim fails as a matter of law. We therefore affirm the district court's summary judgment in favor of Howmedica as to this aspect of Brooks's complaint.

DISPOSITION

We reverse the district court's judgment that Brooks's state-law failure-to-warn claim is preempted by federal law. We affirm the court's judgment in favor of Howmedica as to Brooks's claim that Howmedica neglected to comply with federal regulations. We remand the matter for further proceedings consistent with our opinion.

MURPHY, Circuit Judge, dissenting.

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[3] Brooks points to two affidavits and reports from expert witnesses trained in toxicology and safety engineering to support her claim that Howmedica violated FDA regulations. These reports are insufficient to entitle Brooks to prevail. Assuming for argument's sake that Brooks's experts would be qualified to opine that Howmedica violated FDA regulations, *cf. Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147-49 (1999) (holding that all forms of expert testimony must be subjected to *Daubert*'s relevance-and-reliability inquiry), the fact remains that Brooks's experts *did not* opine to this effect. These experts' affidavits and reports fail even to mention the pertinent FDA regulations.

I agree with part of the court's opinion, but I respectfully dissent from the discussion in section A.3. and the conclusion that Brooks' failure to warn claim is not preempted by federal law.

Simplex, the product on which Brooks' lawsuit is based, is regulated by a comprehensive set of federal requirements. It is thus unlike the pacemaker in *Lohr* which had no federal requirement specific to the product. *See Lohr* at 493-94. The *Lohr* pacemaker passed through a substantial equivalency process instead of the NDA process which Simplex underwent. *See id.* at 480. During the NDA process the FDA reviewed, and in some instances drafted, every word of the product labeling for Simplex. This labeling cannot be changed without FDA approval. In the case of Simplex, unlike for the *Lohr* pacemaker, "the Federal Government [ ] weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved . . . , and implemented that conclusion via a specific mandate on manufacturers or producers." *Id.* at 501.

A state requirement of general applicability will be preempted under the MDA if there is a federal requirement specific to the device and if the state requirement has the effect of imposing a substantive requirement on the device different from, or in addition to, the federal requirement. *See id.* at 500. The failure to warn claim brought by Brooks seeks to impose a substantive requirement on Simplex because if it were to prevail, Howmedica would need to add warnings about the effects of inhaling methyl methacrylate vapors during the mixing process in order to escape tort liability in Minnesota. This

would be in addition to federal requirements since the labels reviewed and drafted by the FDA do not include these warnings. Thus, the substantive requirement sought by the failure to warn claim would be in addition to the federal requirement specific to Simplex, and the claim is preempted. This conclusion is consistent with results in other federal circuit courts which have concluded that common law failure to warn claims are preempted by the MDA when the device has been approved after a PMA or NDA review. *See Kemp v. Medtronic, Inc.*, 231 F.3d 216, 236-37 (6th Cir. 2000); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 907, 913 (7th Cir. 1997), *cert. denied*, 523 U.S. 1020 (1998); *cf. Papike v. Tambrands, Inc.*, 107 F.3d 737, 741-42 (9th Cir. 1997) (failure to warn claim preempted by FDA labeling regulations regarding toxic shock syndrome), *cert. denied*, 522 U.S. 862 (1997). *But see Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1377 (11th Cir. 1999) (failure to warn claim did not impose a substantive requirement).

In spite of the clear language of the statute which provides for preemption of any state requirement "different from, or in addition to, any requirement applicable under this chapter to the device," 21 U.S.C. § 360k(a), the court says that Congress did not "really mean" the language be taken literally because it was concerned about safety. The legislative history shows, however, that the preemption provision was included within the MDA because of congressional concern that "if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened." H.R.Rep. No. 853, 45 (1976). In respect to Simplex, the FDA worked closely with Howmedica and

thoroughly reviewed and approved the warning labels. To permit state requirements to be added to those imposed by the federal government would frustrate congressional intent because it could result in conflicting labeling requirements in various states, confusion, and unwarranted expense to manufacturers and developers of medical devices.

Since the failure to warn claim in this case falls within the scope of the preemption provision of the MDA, I would affirm the judgment of the district court.

A true copy.

Attest:

CLERK, U.S. COURT OF APPEALS, EIGHTH CIRCUIT.

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

CAROL JEAN BROOKS,

Plaintiff,

v.

HOWMEDICA, INC., a Delaware corporation, Division of PFIZER HOSPITAL PRODUCTS GROUP, INC.; and HOWMEDICA INTERNATIONAL, LTD.,

Defendants.

Case No.
CV-97-656 MJD/RLE

MEMORANDUM OPINION AND ORDER

(Filed Sep. 22, 1999)

Paul A. Strandness and Markus C. Yira, Eckman, Strandness & Egan, P.A., for and on behalf of Plaintiff.

Cooper S. Ashley and Laurie Kindel, Maslon Edelman Borman & Brand, LLP and Thomas Shiah, The Law Offices of Thomas Shiah, Ltd. for and on behalf of Defendants.

INTRODUCTION

Plaintiff, Carol Jean Brooks, ("Brooks") is a former surgical technician. In her Complaint, she alleges that she inhaled methyl methacrylate vapors while mixing Defendant Pfizer Hospital Products Group, Inc., Howmedica, Inc. and Howmedica International, Ltd.'s, ("Howmedica"), Surgical Simplex bone cement ("Simplex"), and that as a result, she has contracted asthma. Plaintiff further alleges that the Simplex label, package insert and material safety data sheets failed to adequately warn her regarding the hazards of inhaling bone cement vapor.

Currently before the Court is Howmedica's motion for summary judgment. Howmedica argues it is entitled to summary judgment on three grounds:

> (1) That Brooks' common law action, premised on failure to warn, is preempted by the federal law that regulates Howmedica's product, Simplex. The 1976 Medical Device Amendments ("MDA") to the federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C.A. 360K(a) (West Supplement, 1998).
>
> (2) That, as a matter of law, Brooks' claim that the Material Safety Data Sheet (MSDS) – which was created pursuant to OSHA regulations – is insufficient as there is no private cause of action for OSHA violations.
>
> (3) That summary judgment is appropriate as Brooks never read or relied upon the documents that she is claiming are insufficient.

FACTUAL BACKGROUND

Simplex Bone Cement

Howmedica manufactures Simplex[1], a bone cement used in orthopedic surgery. Simplex is packaged and sold as two sterile components. Mixing the components causes

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[1] Howmedica asserts that it used to market two Simplex Bone cement products. These products are identical except that one contained an ingredient that made it visible when x-rayed. The demand for the visible product was so high that in 1986, Howmedica discontinued the second bone cement. Brooks has not addressed the existence of two Simplex products and Howmedica has stated that Simplex refers to both products, unless otherwise specified.

an exothermic polymeric reaction, which initially forms a soft pliable mass. As the reaction progresses, the mass forms a hard cement-like complex which has been used in joint replacement surgeries since the late 1960's. Lawler Aff. at ¶ 7

One component of Simplex is a methyl methacrylate monomer, a colorless liquid packaged in a 20-milliliter ampule; the other component is a polymer powder consisting of a polymethyl methacrylate, methyl methacrylate-stryene-copolymer, and barium sulfate for radiopacity. When the monomer is mixed with the polymer, methyl methacrylate vapors are released. *Id.* at ¶¶ 7, 8. The product also contains DMPT (N,N-DIMETHYL-P-TOLUIDINE). OSHA classifies this substance and methyl methacrylate as hazardous chemicals. Junghans Aff. at ¶ 3. Both of these substances are considered sensitizers.[2] Pearson Aff. at ¶5.

Before Simplex could be sold in the United States, the product underwent review by the FDA. During this review period, which occurred between 1969 and 1971, the regulatory scheme then in place dictated that the FDA review occur pursuant to the New Drug Application process. ("NDA"). FDA approval was obtained to sell Simplex in 1971. Lawler Aff. ¶ 4.

In 1976, Congress enacted the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act in response to mounting consumer and regulatory

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[2] A sensitizer is an agent which, if breathed by certain individuals, can lead to the development of occupational asthma. Strandness Aff., Ex. C. at 17

concern. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996). Under the MDA, medical devices are classified into three categories. Class I devices are those medical devices that pose no unreasonable risk of illness or injury, and are subject to minimal regulation. 21 U.S.C. § 360c(a)(1)(A). Class II devices are those medical devices that are potentially more harmful than Class I devices, and may be marketed without prior approval by the FDA. Manufacturers of such devices, however, must comply with performance regulations. *Id.* § 360c(a)(1)(B). Class III devices are those medical devices that present a potential for unreasonable risk or injury, or are "purported or represented to be for a use in support or sustain human life or for a use which is of substantial importance in preventing impairment of human health. *Id.* § 360c(a)(1)(C). Class III devices are heavily regulated, and manufacturers of such devices are required to undergo a rigorous approval process known as premarket approval. *Id.*

Bone cement was considered a transitional device under the MDA and was reclassified as a Class III medical device. 21 U.S.C. § 360j(l). Because Simplex had already been subject to FDA review through the NDA process, FDA regulations did not require completion of the premarket approval process established by the MDA. Lawler Aff. ¶ 45.

Premarket approval (PMA).

First, Howmedica asserts that the NDA process, to which Simplex was subjected, is the legal and functional equivalent of the premarket approval process provided for by the MDA. Brooks does not dispute this assertion.

Under the NDA process, Howmedica was required to provide the FDA with a body of information to determine the safety of Simplex. Specifically, FDA approval required the completion of clinical trials, long term carcinogenicity and toxicity studies and animal trials. Lawler Aff. ¶ 12. The FDA also wrote or reviewed the wording of Howmedica's product labeling, which included the package insert and external package labeling. *Id.* The NDA process also required Howmedica representatives to meet with FDA officials on a number of occasions to review the status and progress of the approval process. *Id.*

Specifically with respect to the warnings on the Simplex package and package insert, Howmedica representatives met with doctors with the FDA to discuss, among other things, the content of the product labels. *Id.* ¶ 20. Howmedica was informed that the "FDA is writing label copy and package insert." *Id.*, Ex. G, ¶ 8. The NDA would not be approved until the FDA had seen the actual printed labels and the final Simplex package. *Id.* On August 4, 1971, Dr. Gyarfas of the FDA sent copies of drafts, written by FDA Drs. Gyarfas, Griesby and Sunnenblick, of the package insert to Howmedica. *Id.* The package insert, as drafted by the FDA doctors, included the following warning:

> As the liquid monomer is highly volatile and flammable, the operative room should be provided with adequate air circulation. Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated vapors of the monomer which may produce irritation of the respiratory tract, eyes, and possibly the liver.

Id., Ex. I. Each label, and every word included in the package insert, has been reviewed by the FDA, and approved or drafted by the FDA. *Id.*, Ex. J.

On April 18, 1973, in response to the results of an eighteen-month Simplex implantation in rats, FDA Director Dr. George F. Leong recommended a revision to the "Warning" section of the labeling to reflect the results of the study. *Id.*, ¶ 33. Howmedica incorporated the "recommendation" of Dr. Leong, and also proposed the following additional language:

> The liquid component is a powerful lipid solvent, and may also act as a sensitizer in certain individuals. It should not be allowed to come into direct contact with sensitive tissues or be absorbed by the body.

Id. Howmedica suggested inclusion of this additional language in response to a questionnaire completed by forty-three surgeons, that indicated that seven cases of contact dermatitis from exposure to Simplex had been observed. *Id.* The FDA approved the additional modification, but changed the language to read:

> The liquid component is a powerful lipid solvent. It has caused contact dermatitis in susceptible individuals. Wearing of a second pair of surgical gloves and strict adherence to the mixing instructions may diminish the possibility of hypersensitivity reactions. The compound should not be allowed to come into direct contact with sensitive tissues or be absorbed by the body.

Id.

In 1976, in response to an official review of the issue of inhalation toxicity of methyl methacrylate vapors by operating room personnel, Howmedica was required by the FDA to send out a "Dear Doctor" letter. In this letter, Howmedica was required to inform those doctors that used Simplex of studies relating to inhalation of methyl methacrylate, and to direct the doctors attention to the warning in the package insert regarding the volatility of the liquid monomer, and that caution should be taken when mixing the components "to prevent excessive exposure to the concentrated vapors of the monomer which may produce irritation of the respiratory tract . . . " *Id.* Ex. Z at 2-3. The contents of the "Dear Doctor" letter were approved by the FDA and the letter was forwarded to purchasers in 1976. *Id.* ¶ 44. At that time St. Lukes Hospital, Brooks' employer, was purchasing Simplex and would have received a letter.

The Plaintiff

Brooks worked as a surgical technician until March 1995, when due to health problems, she was no longer able to continue working. As a surgical technical, Brooks was required to mix by hand bone cement. She first mixed bone cement in 1978[3] when she worked at St. Mary's hospital in Duluth. From December 1982 to 1994, Brooks was employed by St. Luke's Hospital in Duluth. After the spring of 1983, she worked almost exclusively in the orthopedic surgical department. Over the years,

---

[3] Brooks is unable to identify the brand of bone cement that she was required to work with during this period.

the number of surgeries that required use of Simplex bone cement gradually increased. By 1992, Brooks estimates that she was exposed to Simplex during ten operations per week, and would inhale the fumes that were given off by the bone cement during the mixing process.

Beginning in 1989, Brooks began to cough during the days that she was at work. Stradness Aff., Ex. B at 105. The cough got progressively worse, eventually causing her to seek medical attention in 1991. At that time, she learned that she had an asthma condition, but continued working. In the fall of 1991, she went to see Dr. Kostamo, an occupational medicine physician at St. Lukes. Dr. Kostamo diagnosed Brooks as having "Chronic Cough with asthma features" but was unsure of the causation. Stradness Aff., Ex. C at 42. Thereafter, Dr. Kostamo began to investigate the cause of Brooks' asthma by reviewing the Material Safety Data Sheet (MSDS) required by OSHA for the Simplex product. The MSDS did not provide any information or warnings of a relationship between asthma and the components contained in Simplex. Dr. Kostamo also telephoned a chemist at Howmedica, but through this conversation was not able to conclude that methyl methacrylate or any other material was a trigger of Brooks's asthma. Brooks was released back to work without restriction, which included ongoing exposure to a number of chemicals, including Simplex, Kindel Aff., Ex. B, at 178.

In April 1992, Brooks had an acute asthma attack which resulted in her hospitalization for ten days. She was allowed to return to work, but with restrictions

including no exposure to methyl methacrylate and limited exposure to other chemicals. Kindel Aff. Ex. E. Thereafter, Brooks was never again exposed to bone cement. *Id.*, Ex. B at 111-112.

Brooks claims that the packaging for Simplex contained no warnings whatsoever of the dangers of breathing the product while mixing it. Brooks Aff. Brooks further asserts that she has been unable to work since March 1995. *Id.* at 266. Her case against Howmedica is premised on the state common law claim of a failure to warn of the danger associated with the product.

STANDARD OF REVIEW

Summary judgment is appropriate if there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986); *Unigroup, Inc. v. O'Rourke Storage & Transfer Co.*, 980 F.2d 1217, 1219-20 (8th Cir. 1992). The court determines materiality from the substantive law governing the claim. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Disputes over facts that might affect the outcome of the lawsuit according to applicable substantive law are material. *Id.* A material fact dispute is "genuine" if the evidence is sufficient to allow a reasonable jury to return a verdict for the nonmoving party. *Id.* at 248-49.

ARGUMENT

1. Preemption

Howmedica argues it is entitled to summary judgment, as Brooks' common law claim of failure to warn is preempted by the MDA.

The express preemption provision of the MDA provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The United States Supreme Court has addressed the scope of the MDA's preemption clause in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). *Lohr* involved a Class III medical device approved pursuant to the substantial equivalency process – a process that allows manufacturers to market devices that are substantially similar to devices already on the market, pending premarket approval. *Id.*, at 477. Unlike the premarket approval process, the purpose of which is to ensure safety, the purpose of the substantial equivalency process is to allow competition during the final approval process. *Id.* at 493.

In addressing the preemption issue, the majority began its analysis by restating the principle that Congress does not cavalierly preempt state law causes of action, given the state's historic police powers over matters of health and safety. *Id.* at 485. It then noted that " 'the purpose of Congress is the ultimate touchstone' in every preemption case." *Id.* With these principles in mind, the Court began its analysis of the scope of the MDA preemption provision.

The Court concluded that the MDA preemption provision was highly ambiguous. *Id.* at 495-496. Because of the ambiguity, and the fact that Congress delegated its authority to the FDA to implement the provisions of the MDA, the Court determined that the FDA is "uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress' . . . and therefore, whether it should be preempted." *Id.* at 496. Thus, the Court determined that substantial weight should be given to the FDA's view of the preemption provision. *Id.*

The FDA has promulgated regulations as to the scope of the MDA preemption provision. 21 C.F.R. § 808.1. According to these regulations:

> (d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific food and

> Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:
>
> > (1) Section 5219a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

Id. Based on this language, the Court determined that the MDA only preempts state law claims when the state and federal requirements meet certain criteria.

> State requirements must be 'with respect to' medical devices and 'different from, or in addition to' federal requirements. State requirements must also relate 'to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device,' and the regulations provide that state requirements of 'general applicability' are not preempted except where they have 'the effect of establishing a substantive requirement for a specific device.' Moreover, federal requirements must be 'applicable to the device' in question, and, according to the regulations, preempt state law only if they are 'specific counterpart regulations' or 'specific' to a 'particular device.' The statute and the

> regulations, therefore, require a careful comparison between the allegedly preempting federal requirement and the allegedly preempted state requirement to determine whether they fall within the intended preemptive scope of the statute and regulations.

Id. at 500.

The Court in *Lohr* divided on whether state common law actions could ever be preempted by the MDA. Justice Stevens, writing for himself and three other justices, determined that "given the critical importance of device-specificity in our (and the FDA's) construction of § 360k, it is apparent that few, if any, common-law duties have been preempted by this statute. It will be rare indeed for a court hearing a decree that has 'the effect of establishing a substantive requirement for a specific device." *Id.* 502-503. These justices declined to determine, however, whether §360k(a) ever preempted common law actions.

Justice O'Connor, writing for herself and three justices, disagreed with the analysis of the plurality, finding "state common-law damages actions do impose 'requirements' and are therefore preempted where such requirement would differ from those imposed by the FDCA." *Id.* at 509. Justice Breyer, in his separate concurring opinion, also disagreed with the plurality's conclusion that the MDA preemption of common law claims will be "few" or "rare". *Id.*, at 508. Justice Breyer basically agreed with Justice O'Connor's discussion and conclusion that the MDA will "sometimes preempt a state law tort." *Id.* at 503. "One can easily read the word 'requirement' as including the legal requirements that grow out of the

application, in particular circumstances, of a State's tort law." *Id.* at 504.

Since *Lohr* was decided, lower courts have interpreted the preemptive effect of the MDA inconsistently. In *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090, 1096 (6th Cir. 1997) *cert. denied*, ___ U.S. ___, 118 S.Ct. 850 (1998), the court was asked to determine whether certain state law claims concerning a medical device that had been exempted from the PMA process pursuant to the "Investigational Device Exemption" ("IDE") were preempted by the MDA. The court began its analysis by noting that central to the outcome of *Lohr* was the fact that the device at issue had received FDA approval via the substantial equivalency process – a process that focuses on equivalency rather than safety. *Id.* at 1096. By contrast, the purpose of the IDE is to promote safety and innovation. *Id.* at 1099. The court also noted that "[u]nlike the general federal requirements discussed in Medtronic, the regulations governing investigational devices are essentially device specific." *Id.* at 1097. The court further noted that although the plurality held that "few, in any, common-law duties have been preempted", a majority of the Court (Justices Breyer, O'Connor, Scalia, Thomas and Chief Justice Rehnquist) agreed that the MDA preemption provision could preempt state law causes of action where the state law differs from or is in addition to requirements imposed by the MDA. *Id.* 1096-1097.

With respect to the plaintiff's state law claims of inadequate warning, the court determined that the federal regulations regarding investigational devices were specific requirements. The court went on to hold that as the state law claim of inadequate warning would impede

the implementation and enforcement of specific federal requirements, the state law claims were preempted. *Id.* at 1100.

In *Chambers v. Osteonics Corporation,* 109 F.3d 1243, 1247 (7th Cir. 1997), the Seventh Circuit similarly held that state common law claims of strict liability and breach of implied warranty concerning a device approved pursuant to the IDE were preempted, because such claims imposed greater requirements on the manufacturer that the FDA requirements. *See also, Papike v. Tambrands Inc.,* 107 F.3d 737 (9th Cir. 1997) *cert. denied,* ___ U.S. ___, 118 S.Ct. 166 (1997) (state law claim of failure to warn preempted by specific federal requirements that mandated the specific substantive content of the warning.) The court further held, however, that a negligent manufacturing claim that merely alleges that a manufacturer did not follow the FDA requirements imposes no greater requirements on a manufacturer and is thus not preempted. *Chambers,* at 1248.

Following the approach adopted by the courts in *Martin, Chambers* and *Papike,* the Seventh Circuit held that state common law claims of mislabeling, misbranding and adulterations concerning a medical device that obtained FDA approval through the premarket approval process were preempted. *Mitchell v. Collagen Corporation,* 126 F.3d 902 (7th Cir. 1997) *cert. denied,* ___ U.S. ___, 118 S.Ct. 1300 (1998). "[T]o the extent that these allegations claim that Collagen has incurred liability under state law despite its conformity to the requirements of the PMA, the state law claims must be preempted. Permitting such claims would add requirements that are "different from, or in addition to" those established through the PMA

process." *Id.* A claim that alleged that a manufacturer failed to meet the standards set forth in the PMA process would not necessarily be preempted. *Id.*

Two other circuits have interpreted *Lohr* quite differently. In *Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997), the court determined that with respect to the device at issue, the FDA had imposed specific requirements as to the device's labeling for purposes of the preemption analysis. However, the court went on to hold that common law claims of failure to warn were not specifically developed with respect to medical devices. Because the standard of care involved in the state law claim was "not the type of device-specific requirement that would threaten the MDA's federal interests, the state law claim was not preempted. *Id.* at 789.

More recently, the Eleventh Circuit Court of Appeals ruled that the premarket approval process does not impose any ascertainable requirement upon the device for purposes of the preemption analysis. *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir.) *r'hg and r'hg en banc denied*, 180 F.3d 276 (1999).

> In the typical PMA review and approval and, more particularly, in the context of the 4004/M PMA, the FDA issues no regulation, order, or any other state of its substantive benchmark. . . . The approval represents only a finding that the manufacturer's proposal to market a device has reasonably assured the FDA of the device's safety and effectiveness. Nor does the FDA's willingness to notify an applicant of deficiencies and to propose modifications to the PMA application add further force to Medtronic's argument for preemption, because an applicant who

> corrects or modifies a deficient PMA application before receiving the FDA's approval stands in no better position than an applicant whose initial PMA application was flawless. In either case, the FDA enters a finding that the applicant has furnished the relevant assurances and therefore may begin to market its device. In neither case, however, does the approval provide any indication of what (if any) specific substantive requirements the FDA may have applied to reach that result.

Id. at 1375.

Brooks asks this Court to interpret the *Lohr* decision, consistent with the interpretations adopted by the courts in *Oja*, and *Goodlin*. Brooks argues that her common law claims are general obligations applicable to all manufacturers and are not requirements specifically established for medical devices. She further argues that the review process carried out by the FDA, be it the NDA process or the premarket approval process, does not impose specific requirements for purposes of determining preemption. In support of this position, Brooks cites to a proposed FDA rule concerning the scope of the MDA preemption provision. Although this Court recognizes that deference is given FDA regulations in determining the scope of preemption, *Lohr*, at 496, this Court should not give deference to a proposed rule, however, until it is final. *In re Appletree Markets, Inc.*, 19 F.3d 969, 973 (5th 1994). Accordingly, this court will not consider the proposed rule concerning MDA preemption.

The Eighth Circuit has yet to issue an opinion on the scope of the MDA's preemption post *Lohr*. In a case decided before *Lohr*, the Eighth Circuit interpreted the

MDA preemption provision as preempting a state tort claim where 1) the FDA has established regulations specific to the medical device at issue, 2) the state claim imposes a requirement different from, or in addition to, any FDA requirement for the device, and 3) the claim relates to the safety or effectiveness of the device, or to any other matter included in an MDA requirement for the device. *Martello v. Ciba Vision Corporation,* 42 F.3d 1167, 1168 (8th Cir. 1994) *cert. denied,* 515 U.S. 1161 (1995). The court further held that the premarket approval process is a specific requirement for a device within the meaning of the MDA and the relevant federal regulations. *Id.* at 1169. Because the plaintiff's claims dealt directly with the safety and effectiveness of the product at issue and would add requirements in areas reviewed by the premarket approval process, the state law claims were preempted. *Id.*

In a case subsequent to *Lohr,* the Eighth Circuit addressed a preemption issue under the Animal Plant and Health Inspection Service (APHIS) regulations, issued under the Virus-Serum-Toxin Act. *Symens v. Smithkline Beecham Corp.,* 152 F.3d 1050 (8th Cir. 1998). In *Symens,* the court determined that common law claims are within the scope of a federal statute or regulation preempting state law "requirements." This holding was based, in part, on the fact that five justices in *Lohr* agreed that a federal statute preempting state law requirements regarding medical devices applied to state common law claims as well as to state statutes and regulations. *Id.* at 1055.

Martello and *Symens* suggests that the Eighth Circuit would follow the analysis of those courts that have found

that when a device has been subjected to device specific federal regulations, conflicting common law claims are preempted. *See, Chmielewski v. Stryker Sales Corporation,* 966 F.Supp. 839, 843 (D. Minn. 1997). Thus, Brooks' argument that all state common law claims are not preempted because such claims are of general applicability, must be rejected. *Martello* further supports Howmedica's position that the FDA review of Simplex's labeling imposed specific requirements within the meaning of the preemption provision.

This case closely resembles the facts raised in *Papike,* in the case, the FDA specifically mandated the substantive content of tampon labels with regard to TSS. Thus, any claim that the manufacturer's warnings as to TSS were inadequate are preempted. 107 F.3d at 741. In this case, the FDA was primarily responsible for the content of the labeling of Simplex. Howmedica has submitted unrefuted evidence which shows the FDA reviewed, drafted and approved each label and every word contained in the package insert for Simplex. Therefore, to the extent that Brooks' common law claims of failure to warn and inadequate warnings would require Howmedica to include additional language in their labeling and package inserts, such claims are preempted.

2. No evidence of noncompliance with FDA regulations.

Brooks further argues that Howmedica failed to comply with FDA regulations. Such claims are not preempted, as such claims rest on duties that are equivalent to duties imposed under federal regulations. *Lohr,* at 494; *Chambers,* 109 F.3d at 1248. In support, Brooks argues that

she has seen a monograph by Howmedica which details the dangers of excessive inhalation of the vapors, Strandness Aff., Ex. E, at 13, and claims that this information should be included on the labeling pursuant to 21 C.F.R. § 801.109. In addition, Brooks has submitted the affidavits of two experts that have opined that Howmedica's labeling failed to meet the standards generally required by the FDA.

This evidence does not tend to show that Howmedica violated FDA regulations. Howmedica, on the other hand, has submitted the affidavit of Martha Bennett, an FDA expert. Ms. Bennett states that in her professional opinion, Howmedica complied with all applicable FDA rules or regulations pertaining to labeling. As Brooks has failed to submit any contrary evidence, summary judgment is appropriate on any claim that Howmedica failed to comply with FDA rules or regulations.

IT IS HEREBY ORDER that Howmedica's Motion for Summary Judgment is GRANTED. Plaintiff Carol Jean Brooks' Complaint is hereby DISMISSED WITH PREJUDICE.

Date: 9-21-99

/s/ Michael J. Davis
Michael J. Davis
United States
District Court

Supreme Court, U.S.
FILED
APR 12 2002
CLERK

(2)

No. 01-1333

In the
Supreme Court of the United States

Carol Jean Brooks,

Petitioner,

vs.

Howmedica Inc., a Delaware corporation
and a division of Pfizer Hospital Products Group;
Pfizer Inc.; and Howmedica International Ltd.

Respondents.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

BRIEF IN OPPOSITION

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381P

QUESTION PRESENTED

Does the express preemption provision in the Medical Device Amendments ("MDA") to the Food Drug and Cosmetic Act, 21 U.S.C. § 360k(a), preempt a state law failure-to-warn claim that asserts that the labeling on Simplex bone cement did not adequately warn users of alleged respiratory risks associated with the methyl methacrylate vapors produced when Simplex is prepared, where the Food and Drug Administration was aware of possible respiratory risks associated with methyl methacrylate, was directly involved in drafting and reviewing Simplex's warnings in light of these risks, and concluded through the MDA's "pre-market approval" process that Simplex and its labels were safe and effective in their approved form?

CORPORATE DISCLOSURE STATEMENT

Howmedica Inc. is now known as MTG Divestitures, Inc. It is wholly owned by Warner-Lambert Company, which is a wholly owned subsidiary of Pfizer Inc.

Pfizer Inc. is publicly traded on the New York Stock Exchange. No publicly held companies own 10% or more of its stock.

Howmedica International Ltd. is now known as MTG Divestitures Limited. It is wholly owned by Pfizer Group Limited, which is an indirect wholly owned subsidiary of Pfizer Inc.

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BRIEF FOR THE RESPONDENTS IN OPPOSITION

Respondents Howmedica Inc., Pfizer Inc., and Howmedica International Ltd. (collectively "Howmedica") respectfully ask the Court to deny the petition filed by Carol Jean Brooks ("Brooks" or "Petitioner") for a writ of certiorari. This case raises the same issues as *Martin v. Medtronic, Inc.*, No. 01-441, and *Kemp v. Medtronic, Inc.*, No. 00-1766, both of which this Court recently declined to review. *See Martin*, 122 S. Ct. 907 (2002); *Kemp*, 122 S. Ct. 48 (2001). The short interval since then has not changed the fact that the circuit courts and state courts of last resort are largely in agreement on these issues, and the decision below is consistent with the dominant majority view. Furthermore, the present case is narrow and involves some distinctive facts that would make it a poor vehicle for establishing broad precedent. Under these circumstances, this Court's involvement is not necessary nor would it be well advised.

STATEMENT OF THE CASE

The product at issue is surgical Simplex® P Radiopaque bone cement ("Simplex"), which is used during orthopedic surgery. It is an integral part of joint replacement surgery and has been used in thousands of surgical operations in the United States since its approval by the Food and Drug Administration ("FDA") in 1971. Since at least the mid-1970s, the FDA has been aware that the methyl methacrylate vapors released when Simplex is prepared may be harmful to some individuals, and the agency has required changes in Simplex's labeling to reflect its concerns about these vapors. Brooks is a former operating

room nurse who alleges that methyl methacrylate gave her occupational asthma. Essentially, she challenges the FDA's judgment about the content of Simplex's labeling, and claims that the labeling failed to satisfy Howmedica's duty to warn under Minnesota common law, even though "[t]he FDA reviewed every word that appeared on Simplex labels," (5a) and "was deeply involved in drafting and editing the warnings" throughout the period of Brooks' exposure to the product (27a).

FDA Regulation of PMA Devices

Since 1976, the FDA has regulated Simplex as a Class III medical device under the Medical Device Amendments ("MDA") to the Food Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 - 397 (2000 & Supp. 2001). A Class III device can take more than one path to the market under the MDA. Simplex is on the market through the Premarket Approval ("PMA") process, in which the FDA approves a product as "reasonably safe and effective."[1] *See id.* §§ 360c(a)(1)(C), 360e(d)(2). Petitioner acknowledges that Simplex is a PMA device, but her factual statement does not accurately reflect the nature of the FDA's control over such devices and their labels.

Both before and after a PMA product is on the market, the FDA exercises comprehensive and meticulous control over many aspects of the product, including its labels. At the initial approval stage, the manufacturer must provide the FDA with "reasonable assurance" that the device is both safe and effective. *See id.* §§ 360c(a)(1)(C), 360e(d)(2). As this Court

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[1] Initially, Simplex entered the market through the New Drug Application process, which is equivalent to the PMA process. It has been a PMA device since 1976. *See infra*, at 8-9.

recognized in *Lohr*, "Despite its relatively innocuous phrasing, the process of establishing this 'reasonable assurance,' . . . , is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996).

The FDA's protection of the public does not end with its initial approval of a device. The FDA receives regular reports from device manufacturers and certain health care facilities about the performance of PMA devices. 21 U.S.C. § 355(k), 21 C.F.R. §§ 803.10, 803.50-.58, 814.84. Based on information from these sources and others, the FDA may take a variety of actions. It may require a manufacturer to change any regulated aspect of the device, including its labels. 21 C.F.R. § 814.82(a)(3). The FDA is also authorized to recall a device or require that a manufacturer provide notice or refunds to the public, or repair or replace a product. 21 U.S.C. § 360h. The MDA also includes some criminal enforcement provisions. *See* 21 U.S.C. §§ 331, 333.

Contrary to Petitioner's assertion, the PMA process results in specific government dictates about device design, manufacturing, and labeling. Although the applicant proposes a product's initial specifications and labeling, the specifications and labeling that are ultimately approved can originate with the FDA. This is the case, for example, when (as here) the agency requires specific changes during the initial approval process or after a product is on the market. Moreover, once the FDA grants PMA approval, the approved specifications cannot be changed without further FDA approval; they therefore become specific government dictates, regardless of whether they

originated with the FDA. *See* 21 C.F.R. §§ 314.70, 814.37, 814.39(a)(2). After all, continued assurance of the device's safety and effectiveness depends on the device remaining the same.

Federal regulations permit a manufacturer to make preliminary changes to a PMA device's labels if the changes "enhance[] the safety of the device or the safety in the use of the device," *id.* § 814.39(d), but ultimately the FDA's judgment controls–if the FDA does not approve the change, the label must return to its prior form, *id.* § 814.80. Moreover, whether a change does "enhance" safety or effectiveness is ultimately determined by the FDA, and a product label that overstates risk may cause a device to be "misbranded." *See* 21 U.S.C. 352(a) (providing that a device is "misbranded . . . [i]f its labeling is false or misleading in any particular").

The FDA's control over PMA devices involves complex science and public policy decisions. With respect to warning labels, for example, the FDA must ensure that devices include "adequate warnings . . . in such manner and form, as are necessary for the protection of users." 21 U.S.C. § 352(f). The FDA recognizes, however, that more warnings do not necessarily mean more safety. *See, e.g., Labeling and Prescription Drug Advertising*, 44 Fed. Reg. 37,434, 37,447 (June 26, 1979) ("The Commissioner believes that including theoretical hazards as contraindications in drug labeling would cause that very important section of the labeling to lose its significance."). Warnings must be sufficiently conspicuous as to render them "likely to be read," considering the other words or statements on the label. 21 U.S.C. § 352(c); *see also* 21 C.F.R. § 801.15 (regarding the required prominence of label statements). As the Eighth Circuit recognized, FDA-mandated

warnings can lose their impact if diluted by warnings with a weaker scientific basis. (24a) In addition, voluminous or overstated warnings might deter doctors or patients from using a beneficial product. Richard M. Cooper, *Drug Labeling and Product Liability: The Role of the Food and Drug Administration*, 41 Food Drug Cosm. L.J. 233, 237-38 (1986). These competing interests, all of which affect the public's health and safety, are considered by the FDA in the course of PMA review. (23a-24a)

In sum, PMA devices and their labels are closely controlled by the FDA. The PMA process ensures that the FDA has the information necessary to determine, on an on-going basis, whether PMA devices are safe and effective, coupled with the authority necessary to ensure that they remain that way.

Preemption: MDA § 360k(a) and Lohr

When Congress enacted the MDA, it expanded the FDA's authority over medical devices and established a comprehensive regulatory regime at the federal level. At the same time, it sought to promote public health by encouraging the development of new medical devices, noting the development of "an increasing number of . . . medical devices, [which] hold the promise of improving the health and longevity of the American people." S. Rep. No. 94-33, at 2 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1071. To support this objective, Congress also sought to protect innovations in device technology from being "stifled by unnecessary restrictions." H.R. Rep. No. 94-853, at 12 (1976). Specifically, Congress attempted to shield medical devices from the "undu[e] burden[]" imposed by differing state regulation by including a "general prohibition o[f] non-Federal regulation." *Id.* at 45.

That prohibition is contained in the MDA's express preemption provision, § 360k(a), which broadly provides that no State may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable . . . to the device" under federal law. 21 U.S.C. § 360k(a).

In addition to this broad express preemption provision, the MDA gives the FDA sole authority to determine whether states may also regulate devices controlled by the FDA. States seeking to impose additional safety requirements must apply for an exemption from preemption, 21 U.S.C. § 360k(b), and the FDA has denied numerous requests submitted by states seeking to impose additional safety requirements, *see, e.g., Exemption from Preemption of State and Local Hearing Aid Requirements*, 45 Fed. Reg. 67,326, 67,331 - 67,335 (Oct. 10, 1980) (discussing the disposition of exemption applications involving hearing aid requirements). The FDA need not find a conflict between state and federal law before denying an exemption. *Id.* at 67,328.

This Court considered the preemptive effect of § 360k(a) in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), in which a divided court held that § 360k(a) did not bar a state tort action challenging the design, manufacture, or labeling of a Class III device that was permitted on the market through the 510k process, a much less rigorous alternative to PMA approval. The 510k process simply requires that a device be established as "substantially equivalent" to a device that was on the market before the MDA was enacted. 518 U.S. at 492-93. The *Lohr* Court explicitly differentiated this process from the PMA process, which it described as "rigorous" and "by no means comparable" to 510k review. *Id.* at 477, 478. The Court

carefully assessed the sort of information reviewed by the FDA and the amount of time the FDA spends on the review, and noted that during the 510k process the FDA is not focused on safety or effectiveness, while these are the central concerns of PMA approval. *Id.* at 477-79, 493.

Although *Lohr*'s holding applies only to devices subject to 510k review, the *Lohr* Court created a basic framework for analyzing express preemption under § 360k(a). First, a majority of the Court found that state common law tort actions could impose specific state "requirements" within the meaning of the statute and thus could be preempted. 518 U.S. at 504-05 (Breyer, J., concurring); *accord. id.* at 509 (O'Connor, J., concurring in part and dissenting in part). Second, a majority held that the details of the federal requirements applicable to the device must be "careful[ly] compar[ed]" to any state requirements that are potentially preempted. *Id.* at 500. Finally, a majority found that only "specific" federal requirements could be preemptive, and only of "specific" state requirements. *Id.*; *accord id.* at 506-07 (Breyer, J., concurring). Under this framework, the Court determined that approval through the 510k process did not preempt the plaintiffs' state law design, manufacturing or labeling claims, primarily because the approval involved only general requirements and focused on substantial equivalence, rather than safety and effectiveness. *Id.* at 494, 502; *accord id.* at 508 (Breyer, J., concurring).

As interpreted in *Lohr*, § 360k(a) will preempt many claims against the manufacturers of PMA devices, consistent with the express terms of the statute. The MDA does not leave the public without any source of compensation for damage caused by defective products, however. If a device fails to comply with federal safety requirements, such claims are not

preempted. *Lohr*, 518 U.S. at 495; *see also id.* at 513 (O'Connor, J., concurring in part and dissenting in part). Furthermore, as noted above, claims based on less rigorously regulated 510k products are not preempted. *Id.* at 494, 502; *accord id.* at 508 (Breyer, J., concurring).

The Extensive Regulatory History of Simplex and Its Labeling

When Simplex was first proposed for potential sale in the United States in 1969, the federal government had no premarket approval authority over most medical devices. This authority extended only to "new drugs," as defined by the FDCA. *See* 21 U.S.C. §§ 321(p), 355. Because the definition of "new drugs" was quite broad, the FDA occasionally used this authority to assert premarket control over medical devices, and it did so with respect to Simplex. (4a-5a)

The New Drug Application ("NDA") process, through which Simplex obtained premarket approval,

> required Howmedica to disclose details of animal studies, manufacturing and quality control procedures, the identification of possible side effects, results of clinical trials, summaries of surgical cases and post-operative complications, long-term toxicity, and carcinogenicity studies. The process also produced reports from the investigational use of Simplex by sixty-seven physicians in 1,408 hip replacements which involved 2,800 preparations of the product.

(5a) *See also* 21 U.S.C. § 355(b) (describing the required contents of an NDA).

The NDA also included the proposed design and content for all Simplex labeling, "including labels for a vial, a pouch, two internal boxes, an outer box, and a package insert." (5a) While the NDA was pending, the FDA itself wrote label copy and ultimately instructed Howmedica to include in the package insert the following warning regarding operating room ventilation and exposure to the methyl methacrylate vapors–the very heart of Brooks' failure-to-warn claim:

> As the liquid monomer is highly volatile and flammable, the operative room should be provided with adequate air circulation. Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated vapors of the monomer which may produce irritation of the respiratory tract, eyes, and possibly the liver.

(6a) Therefore, as a result of the NDA process, "[t]he FDA reviewed every word that appeared on Simplex labels, and the FDA drafted the language that was used in the package insert." (5a)

Howmedica was informed on October 7, 1971 that the FDA had approved Simplex for sale in the United States, based on the agency's determination that the product was "safe and effective for use as recommended in the submitted labeling." (6a) As discussed above, one condition of approval was that Howmedica could not change the approved labeling without FDA approval. (7a) *See* 21 C.F.R. § 130.9(a)(2) (1971).

As the Eighth Circuit found, "[i]t is undisputed that Simplex has been heavily regulated by the FDA since it entered the market. . . ." (4a) With respect to labeling, "the FDA ha[d]

continuing authority and responsibility to control the content of any information or warnings Howmedica provide[d] Simplex users." (7a) In fact, "[t]he FDA was deeply involved in drafting and editing the warnings on the Simplex label and package [insert], beginning with the product's approval in 1971 and continuing on through the period in which Brooks was exposed to it." (27a)

For example, in the early 1970s, the FDA drafted language about the risk of some individuals contracting contact dermatitis from methyl methacrylate, and required Howmedica to include the new language in the package insert. (8a) The latest labeling change involving methyl methacrylate was made in 1986, when the FDA approved Howmedica's request to add language to the package insert warning that soft contact lenses should not be worn where Simplex is being prepared. (10a)

Significantly, the regulatory history in this case reveals that the FDA was aware of the very subject of Petitioner's claim–the potential occupational risks associated with methyl methacrylate vapors–and told manufacturers exactly what information they should provide to users about this topic. As the Eighth Circuit held, "[t]he record demonstrates that the FDA was aware of a possible link between methyl methacrylate and respiratory damage for several decades, and the agency required Howmedica to take specific steps in response." (26a) In early 1975, the FDA required all United States bone cement manufacturers to participate in a review of the potential occupational hazards associated with methyl methacrylate. During the course of this review, the FDA required Howmedica to change the paragraph of the package insert that the FDA had originally drafted, to emphasize the need for adequate ventilation where Simplex is being prepared. (8a-9a) Later, as

a result of the review, the agency directed manufacturers, including Howmedica, to send a "Dear Doctor" letter to operating room supervisors, orthopedic surgeons and hospital administrators. (9a) Among other things, the letter cautioned that if operating room personnel develop an allergic response to the vapors, they should avoid using Simplex. (*Id.*) The letter also repeated relevant language from the package insert. (*Id.*)

After passage of the MDA in 1976, Simplex was automatically reclassified by statute to a Class III medical device. (7a (citing 21 U.S.C. § 360j(*l*)(1)) Because it had been approved through the comparably rigorous NDA process, it was deemed by statute to have PMA approval, 21 U.S.C. § 360j(*l*)(3)(A)(i), and it has been treated as a PMA device ever since.

There is no evidence in this case that Howmedica failed to follow the FDA's dictates in any respect throughout Simplex's long history. Howmedica has provided the FDA with all of the required reports, and at all times Simplex's labels have been in the form approved and required by the FDA.[2]

Petitioner's Case in the Lower Courts

Brooks filed this action in the United States District Court for the District of Minnesota on March 18, 1997, claiming that Simplex's labeling failed to adequately warn her of alleged

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[2] Petitioner asserted a claim based on noncompliance earlier in this case, but every judge who has considered the issue concluded that there is no evidence of noncompliance. (29a, 42a, 63a-65a, 87a) Furthermore, Petitioner has dropped any such claim by omitting it from her Petition. *See* S. Ct. R. 14.1(a).

risks associated with preparing the product. The complaint contained no claims based on Simplex's design or manufacturing, or any aspect of the product other than its labeling. (3a, 46a, 76a) To support her claim, Brooks retained a purported expert, who prepared alternative labeling that differs considerably in both form and content from the labeling approved by the FDA. (23a n.10) As the Eighth Circuit observed, the proposed revisions "includ[e] additional language and colorful pictographs." (*Id.*) The crux of Brooks' case is that Howmedica failed to satisfy its common law duty, because its labeling was not in this form, but rather in the form drafted and mandated by the FDA.

On September 21, 1999, the district court granted Howmedica's motion for summary judgment, holding that § 360k(a) of the MDA preempts Brooks' common law claims "[t]o the extent that [those claims] would require Howmedica to include additional language in their labeling and package inserts." (86a) In reaching this conclusion, the court relied in part on Eighth Circuit pre-*Lohr* precedent, *Martello v. Ciba Vision Corp.*, which held, among other things, that the MDA preempts common law tort claims that challenge a PMA product's labeling and warnings. 42 F.3d 1167 (8th Cir. 1994), *cert. denied*, 515 U.S. 1161 (1995). After careful consideration, the district court rejected Brooks' argument that this precedent did not survive *Lohr*.

On appeal to the Eighth Circuit, the panel unanimously agreed that, for purposes of preemption, common law claims can impose state requirements, and PMA devices are subject to federal requirements. (54a, 57a, 65a) With one judge dissenting, however, the panel held that Brooks' claim was nevertheless permitted by § 360k(a). (66a) At Howmedica's

request, the Eighth Circuit agreed to review the case en banc and vacated the panel decision.

Like the district court and the panel, the en banc Eighth Circuit agreed unanimously that Simplex is subject to specific federal requirements, and that it would also be subject to state requirements if Brooks' common law claim were permitted to proceed. (22a) With respect to federal requirements, the court took note of this Court's observation that the 510k and PMA processes are "by no means comparable," and recognized that because Simplex is a PMA device, "[t]he facts in the case before the court are very different from those in *Lohr*." (20a (quoting 518 U.S. at 478)). Whereas the 510k process "did not require the FDA to be involved in the drafting or approval of the [label at issue in *Lohr*]," the Eighth Circuit noted, "[t]he FDA drafted or approved every word of the Simplex label, and any changes were subject to close FDA scrutiny." (19a-20a)

In analyzing the presence of a state law requirement, the Eighth Circuit simply followed *Lohr*, noting that "five justices concurred in Justice O'Connor's statement that § 360k 'clearly preempts any state common-law action that would impose a requirement different from, or in addition to' a specific federal requirement." (17a-18a (quoting 518 U.S. at 511))

Having recognized that federal requirements determined the form and content of Simplex's labels, and that Brooks' common law claim sought to require a different form and content, seven of the nine sitting judges concluded that the common law claim was preempted. (22a) To support this conclusion, the court noted that the situation was analogous to the illustration provided by Justice Breyer in *Lohr*, in which he "pointed out that if a jury were to find negligence in the use of

a wire longer than one inch in the manufacture of a hearing aid when the FDA had required a two-inch wire, there would be federal preemption as surely as if a state regulation were to impose such a limitation." (22a-23a (citing 518 U.S. at 504 (Breyer, J., concurring))) The original panel majority dissented, on the same grounds expressed in the vacated panel opinion. (30a-42a)

REASONS FOR DENYING THE PETITION

Petitioner has not demonstrated any "compelling reason" for this Court to review the decision below. *See* S. Ct. R. 10. A large and growing majority of circuit courts and state courts of last resort are in agreement, and the Eighth Circuit's position is consistent with the majority view. This Court is not compelled to act simply because of the presence of one or two arguably aberrant decisions, which may well be distinguished or reversed by the circuits themselves. Furthermore, while the broad issue of the scope of § 360k(a) may have nationwide importance, this case is narrow and would not establish precedent on this broad issue. In any event, given the FDA's direct involvement in drafting and controlling the content of Simplex's labels, and the agency's specific consideration of the risks Petitioner complains of, the Eighth Circuit's decision is plainly correct.

I. THIS COURT NEED NOT ADDRESS THE ISSUES RAISED BY THIS CASE, BECAUSE THE LOWER COURTS ARE NOT DEEPLY DIVIDED.

The decisions of circuit courts and state courts of last resort reveal that although the courts often describe the question of MDA preemption as difficult, they are nevertheless answering

the question with a fair amount of consistency, and a consensus is growing in favor of the well-reasoned analysis applied by the court below. Furthermore, this Court's recent decision in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), provides the lower courts with additional guidance about the nature of FDA authority, and, given time, will advance the process of agreement.

A. The Disagreement Is Far More Limited and Will Be More Easily Resolved Than Petitioner Asserts.

Dissatisfied with the fate of her case below, Petitioner hopes to convince this Court that there is a "compelling reason" for review by arguing that the state and federal courts are "deeply divided" on the scope of § 360k(a). *See* S. Ct. R. 10. In fact, at this point the great weight of authority—particularly recent and well-reasoned authority—supports the decision below in all respects.

1. ***Clear precedent has resulted in wide-spread agreement that common law claims may be preempted by § 360k(a).*** In each of the three decisions previously issued in this case, the judges unanimously agreed that Brooks' common law tort suit seeks to impose state law requirements within the meaning of § 360k(a). (20a, 30a, 54a, 63a, 86a) In light of this Court's precedent, and the decisions of other circuit courts and state courts of last resort, the Eighth Circuit's conclusion in this regard is entirely uncontroversial.

In *Lohr*, Justice O'Connor, writing on behalf of four Justices, concluded that "state common law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA."

Lohr, 518 U.S. at 509. This conclusion is endorsed by Justice Breyer, writing separately, who states, "insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action." *Id.* at 504-05; *see also id.* at 503 (Breyer, J. concurring) ("I basically agree with Justice O'Connor's discussion of this point and with her conclusion."). Following *Lohr*, the vast majority of courts to consider this issue have agreed that state common law claims can be preempted by § 360k(a).[3]

This Court recently restated this aspect of *Lohr* in *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000). Every Justice in *Geier* agreed that a majority in *Lohr* concluded that the term "requirement" in the MDA encompasses state law tort claims. 529 U.S. at 867; *accord id.* at 897 (Stevens, J., dissenting). Significantly, Petitioner has cited no post-*Geier* cases supporting the contrary view. Because *Geier* has unambiguously resolved the issue, the current state of general agreement is not likely to devolve into disorder. Furthermore, any aberrant precedent that currently exists is likely to work itself out without this Court's intervention.

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[3] *Martin v. Medtronic, Inc.*, 254 F.3d 573, 580 (5th Cir. 2001), *cert. denied*, 122 S. Ct. 807 (2002); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 230 (6th Cir. 2000), *cert. denied*, 122 S. Ct. 48 (2001); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 912 (7th Cir. 1997), *cert. denied*, 523 U.S. 1020 (1998); *Papike v. Tambrands Inc.*, 107 F.3d 737, 742 (9th Cir.), *cert. denied*, 522 U.S. 862 (1997); *Worthy v. Collagen Corp.*, 967 S.W.2d 360, 371 (Tex.), *cert. denied*, 524 U.S. 954 (1998); *Fry v. Allergan Med. Optics*, 695 A.2d 511, 517 (R.I.), *cert. denied*, 522 U.S. 952 (1997); *Green v. Dolsky*, 685 A.2d 110, 117 (Pa. 1996), *cert. denied*, 520 U.S. 1168 and 520 U.S. 1212 (1997).

2. *A commanding majority agrees that PMA devices are subject to specific federal requirements with preemptive effect.* While *Lohr* did not directly address whether PMA devices are subject to preemptive federal requirements, *Lohr*'s analysis of preemption in the 510k context provides ample guidance to courts considering PMA cases, and their conclusions have been markedly consistent. *Lohr* teaches that preemptive federal requirements are not present where the FDA never formally reviewed a device's safety or efficacy, merely considered whether the device is "substantially equivalent" to a pre-existing device, and "did not 'require' [the device] to take any particular form for any particular reason." 518 U.S. at 493; *accord id.* at 507-08 (Breyer, J., concurring). These circumstances are not present in a PMA case.

Many of the significant–and ultimately decisive–distinctions between the 510k notification process and PMA approval are discussed in *Lohr*. The plurality characterizes the two processes as "by no means comparable," 518 U.S. at 478-79, and continually contrasts the "rigorous" nature of the PMA process with the less-stringent nature of the 510k determination, *see, e.g., id.* at 477-79; *see also id.* at 508 (Breyer, J., concurring) (joining this part of the plurality opinion). *Lohr* points out that during the PMA process the FDA approves a device upon a showing that the design, manufacture and labeling "provide the FDA with a 'reasonable assurance' that the device is both safe and effective," whereas the FDA does not approve these aspects of a device during the 510k process. *Id.* at 477. In short, the Court explained, the 510k process does not protect the public's safety:

> [S]ubstantial equivalence determinations provide little protection to the public. These determinations simply

> compare a post-1976 device to a pre-1976 device to ascertain whether the later device is no more dangerous and no less effective than the earlier device. If the earlier device poses a severe risk or is ineffective, then the later device may also be risky or ineffective.

Id. at 493; *accord id.* at 508 (Breyer, J., concurring).

In addition, *Lohr*'s holding with respect to preemption is explicitly based on the fact that 510k products are subject only to general federal requirements that reflect "entirely generic concerns about device regulation generally," and are applicable to all medical devices. *Id.* at 501. With respect to labeling, for example, the manufacturer of a 510k device is simply required to "include with the device a label containing 'information for use, . . . and any relevant hazards, contraindications, side effects, and precautions.'" *Id.* 497 (quoting 21 C.F.R. 801.109(b) & (c) (1995)). As the *Lohr* Court explained, these general requirements are distinguishable from specific requirements that are based on evaluating specific competing alternatives:

> The generality of [federal labeling and manufacturing requirements] make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.

518 U.S. at 501; *accord id.* at 508 (Breyer, J., concurring).

Courts have had little difficulty recognizing that the requirements imposed on a PMA device fall into the latter category. In the present case, for example, the Eighth Circuit noted that in approving Simplex's labeling, the FDA (*a*) "was deeply involved in drafting and editing the warnings" that were ultimately approved (27a); (*b*) considered a variety of competing interests, such as the value of warnings and the risk that "[w]arnings about dangers with less basis in science or fewer hazards could take attention away from those that present confirmed, higher risks" (24a); and (*c*) required the labeling to remain in its approved form, in the absence of further review and approval (7a-8a). The Eighth Circuit recognized that, because of these facts, the present case falls in the category of cases that was carefully distinguished in *Lohr*.

Looking to *Lohr*, the vast majority of courts to consider PMA cases have come to the same conclusion–that PMA devices are subject to federal requirements with preemptive effect under § 360k(a).[4] By reaching this conclusion here, the Eighth Circuit joined the Fifth, Sixth, and Seventh Circuits, and the courts of last resort in Texas, Rhode Island, and Pennsylvania.[5]

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[4] *Martin*, 254 F.3d at 583-84; *Kemp*, 231 F.3d at 236; *Mitchell*, 126 F.3d at 913-14; *Worthy*, 967 S.W.2d at 376, *Fry*, 695 A.2d at 516; *Green*, 685 A.2d at 117.

[5] *See Martin*, 254 F.3d at 583-84; *Kemp*, 231 F.3d at 236; *Mitchell*, 126 F.3d at 913-14; *Worthy*, 967 S.W.2d at 376, *Fry*, 695 A.2d at 516; *Green*, 685 A.2d at 117. Like the Fifth Circuit, the Eighth Circuit had come to this conclusion before *Lohr*, and concluded that its pre-*Lohr* precedent remained intact. *See* 20a (citing *Martello v. Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994)); *see also Martin*, 254 F.3d at 580-81 (citing *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.

The minority view is expressed in decisions by only one circuit court, *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), and one state supreme court, *Weiland v. Telectronics Pacing Systems, Inc.*, 721 N.E.2d 1149 (Ill. 1999). These cases fail to follow *Lohr*'s direction and are unlikely to survive re-analysis in light of *Buckman*, 121 S. Ct. 1012. *See infra*, at 24-26. Furthermore, just as the Eighth Circuit corrected the aberrant decision of the panel in this case, the Eleventh Circuit's *Goodlin* decision is subject to possible correction by the en banc court–a scenario that becomes increasingly more likely as the trend in favor of the dominant majority view continues.[6]

Petitioner also cites to *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995) *cert. denied*, 518 U.S. 1033 (1996). This case was decided before *Lohr* (and before *Buckman*), so the court did not have the benefit of this Court's description of the rigor of the PMA process. Like the other minority decisions discussed above, *Kennedy* can be corrected without this Court's intervention. In fact, the Ninth Circuit has already begun this process: in *Papike v. Tambrands, Inc.*, it overruled *Kennedy*'s holding that common law tort claims could not impose state law requirements for purposes of preemption. 107 F.3d 737, 741 (9th Cir.), *cert. denied*, 522 U.S. 862 (1997).

1993)).

[6] In addition, the Eighth Circuit distinguished *Goodlin* on its facts. (22a) Other courts may view *Goodlin* as distinguishable, which would further limit its impact.

3. ***There is no disagreement of any consequence among the lower courts about whether the circumstances presented here result in preemption.*** The Fifth, Sixth, Seventh, and now the Eighth Circuits, as well as the highest courts in Texas, Rhode Island, and Pennsylvania, all agree that where a device is subject to PMA requirements, and a common law claim challenges an aspect of the device that is subject to and compliant with those requirements, the common law claim is preempted.[7] Petitioner discusses a lone 1996 decision from the Missouri Supreme Court that comes to a different conclusion, but she herself acknowledges that "the division [among the lower courts] is less pronounced on this subject." Pet. at 24.

The language of § 360k(a) preempts state requirements that are "different from or in addition to" federal requirements applicable to a device under the MDA, as long as they "relate to safety or effectiveness." *Lohr* introduces the idea that this language cannot be read literally, because not all "different" or "additional" requirements would interfere with federal interests. *See, e.g.*, 518 U.S. at 505 (Breyer, J., concurring). There is no ambiguity, however, about how this language applies to a case such as this one. According to Justice Breyer, the "federal and state requirements [must be] closely enough related to trigger pre-emption analysis." *Id.* at 506-07 (Breyer, J., concurring). He illustrates this point with the following example: an FDA requirement that a hearing aid have a 2-inch wire would not preempt a state requirement regarding hearing aid packaging, but would preempt a state requirement for a 1-inch wire. *Id.* at 504-05. In cases such as Brooks', the state requirement is not

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[7] *Brooks*, 273 F.3d at 785, 796-98 (22a-27a); *Martin*, 254 F.3d at 583; *Kemp*, 231 F.3d at 230; *Mitchell*, 126 F.3d at 913; *Worthy*, 967 S.W.2d at 376-77; *Fry*, 695 A.2d at 517; *Green*, 685 A.2d at 413-14.

just "closely . . . related" to the applicable federal requirement, it concerns the identical issue. As the vast majority of courts have recognized, that situation triggers preemption under *Lohr*, and no further showing of a "conflict" is necessary.

Lohr did not restrict the scope of the MDA's broad express preemption provision to cases where preemption would be implied, and the lower courts understand this. *Cf. Buckman*, 531 U.S. 341 (relying on implied preemption principles to expand the preemptive scope of the MDA). In any case, virtually all courts to consider this issue recognize that there is a tension between state and federal law in cases such as this one. Brooks seeks to have a jury decide that the labeling on Simplex did not adequately warn her of possible risks associated with methyl methacrylate. Her claim interferes with the FDA's regulatory authority, because the FDA was aware that methyl methacrylate posed a potential risk to some people; weighed competing considerations such as the scientific basis for a warning, the potential deterrent effect of a warning, and the space needed for other warnings; "was deeply involved in drafting and editing the warnings on the Simplex label and package [insert];" and required Howmedica to obtain approval of any changes. (24a-27a)

Allowing claims such as Brooks' to proceed would interfere with some of the broader purposes of the MDA, as well. In enacting the MDA, Congress recognized that new medical devices "hold the promise of improving the health and longevity of the American people. The Committee wants to encourage their research and development." S. Rep. No. 94-33, at 2 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1071. Preemption of state common law claims that seek to impose different or additional requirements on devices ensures that

"innovations in medical device technology are not stifled by unnecessary restrictions." H.R. Conf. Rep. No. 853, at 1, 12 (1976). The majority view in favor of preemption thus furthers the intent of § 360k(a).

Petitioner discusses only one decision that represents a different view, *Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996) (en banc), *cert. dismissed*, 520 U.S. 1260 (1997). The *Connelly* court looked for an impossibility, asking whether the manufacturer could have provided the additional information to consumers that the plaintiff demanded, while still complying with FDA requirements. Requiring this degree of conflict was an error, because it is not required by the language of § 360k(a), nor is it consistent with *Lohr*. The *Connelly* court compounds this error by misunderstanding the nature of FDA control over PMA devices. The panel majority in the present case espoused a similar view, but it was corrected by the Eighth Circuit en banc. Notably, this Court's intervention was not necessary.

In addition to discussing *Connelly*, Petitioner seeks to create the appearance of controversy by claiming that state claims are preempted in this context only where there is evidence that the FDA considered and rejected the specific view espoused by a plaintiff's common law claim. Like the view discussed above, this view is not shared by the majority of courts. It is also fatally flawed and thus not likely to inspire a substantial following.

The analysis Petitioner espouses is entirely unworkable. In the present case, for example, the FDA was aware of the potential toxicity of methyl methacrylate to certain individuals. The agency initiated a review of the issue, and mandated or approved a number of related label changes. Yet, Petitioner

asserts that the FDA did not consider or reject *her* claim, that the warning of the risk of occupational asthma was inadequate, and that the labeling should have been in the form proposed by her expert. Applying this approach, how close to a plaintiff's position would a rejected change have to be to trigger preemption? The FDA could reject a change proposed to address a certain issue, and a future plaintiff could assert that a slightly different change was required to address the same issue. What degree of variance would prevent preemption? Surely this is not the way Congress intended § 360k(a) to operate, and the vast majority of courts understand that.

Not surprisingly, most courts to consider the issue have not followed the approach urged by Petitioner here. This trend is likely to continue without this Court's involvement. This is particularly true in light of *Buckman*, which elucidates some aspects of the careful regulatory balance the FDA oversees.

B. This Court's Recent Decision in *Buckman* Will Help Resolve Any Remaining Disagreement.

This Court's most recent decision regarding the preemptive effect of the MDA is *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Although *Buckman* focused on implied rather than express preemption, the decision did involve the preemptive effect of the MDA, and has implications for the express preemption issues present in this case. This Court should allow the lower courts time to consider *Buckman*'s implications before addressing preemption issues again. Indeed, *Buckman* may help solidify the already growing trend in favor of the view the Eighth Circuit adopted here and thus eliminate the need for this Court's further involvement.

The plaintiffs in *Buckman* alleged that they were injured by a device manufacturer's "fraud on the FDA." They claimed that but for fraudulent disclosures to the FDA about the device's intended use, the agency would have withheld its approval, and thus they would not have been injured. The Court found such claims to be impliedly preempted by the MDA, noting that "although [*Lohr*] can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim." 121 S. Ct. at 1020.

Buckman can assist courts in determining the scope of § 360k(a) in at least two ways. First, the *Buckman* Court again emphasized how "thorough" the PMA process is as compared to the 510k process that *Lohr* deemed non-preemptive. *See id.* at 1015. The Court explained that PMA devices "complete a thorough review process with the FDA . . . [, which] requires the applicant to demonstrate a 'reasonable assurance' that the device is both 'safe . . . [and] effective . . . ." *Id.* This re-emphasis of a point made in *Lohr* may well influence courts to agree with the Eighth Circuit and other courts that have concluded that *Lohr*'s holding does not preclude preemption in the PMA context. Those few courts that have found otherwise–the most significant of which did so at least three years ago–could reconsider their holdings in light of *Buckman*. Indeed, the Fifth Circuit cited *Buckman* in *Martin v. Medtronic, Inc.*, when contrasting the 510k notification process with PMA approval. 254 F.3d 573, 577, 578 n.4 (5th Cir. 2001), *cert. denied*, 122 S. Ct. 807 (2002).

Second, the *Buckman* Court discussed the "somewhat delicate balance of statutory objectives" that Congress sought

to achieve with the MDA and stressed how allowing "the shadow of 50 states' tort regimes" to compete "with the FDA's detailed regulatory regime" would disrupt that balance. 121 S. Ct. at 1017-18. If courts heed this aspect of *Buckman*, they are not likely to permit suits like Brooks' to proceed. In this case, the MDA's "delicate balance of statutory objectives" requires a careful expert assessment of the potential risks associated with a medical device in order to assure that the risks are stated accurately–neither understated nor overstated. State law product liability suits that challenge the FDA's judgment concerning the adequacy of labels transfer to lay juries a complicated decision–whether or not a warning has a basis in science, and if so, how it should be communicated to accurately state but not overstate the risk–that Congress has entrusted to experts at the FDA. *See, e.g.*, 24a-27a Just as the claim preempted in *Buckman* would have interfered with the FDA's authority to police fraud on the agency, a claim such as Brooks' interferes with the agency's control over product warning labels. This similarity provides ample reason for this Court to allow *Buckman* to percolate among the circuits before again addressing the scope of MDA preemption.

II. THIS CASE IS NOT AN APPROPRIATE VEHICLE BY WHICH TO ESTABLISH BROAD RULES REGARDING PREEMPTION IN THE PMA CONTEXT.

Not only is it unnecessary at this time for this Court to address the issues raised by this case given the state of relative agreement among federal circuit courts and state courts of last resort, this case also is not an appropriate vehicle by which to do so. The case is narrow, and involves some factual

particularities that make it unsuitable for establishing precedent that would be widely followed.

Brooks' case has never involved any claim other than failure to warn. Unlike the plaintiffs in *Kemp* or *Martin* (or the plaintiffs in many product liability cases involving medical devices), Brooks has never based any claims on design or manufacturing. Because this case involves only a failure-to-warn claim, the implications of this case for future cases would rest on a litigant's ability to draw similarities or distinctions between the FDA's control over labeling as opposed to design or manufacturing.

In addition, there is evidence in this case that the FDA itself drafted the warnings at issue and was aware of the potential risk that forms the heart of the Petitioner's claim. As the Eighth Circuit found, the FDA "was deeply involved in drafting and editing [Simplex's warnings], beginning with the product's approval in 1971 and continuing on through the period in which Brooks was exposed to it," (27a); and the agency "was aware of a possible link between methyl methacrylate and respiratory damage for several decades, and . . . required Howmedica to take specific steps in response" (26a). While similar evidence is probably present in the regulatory history of many PMA devices, the record here creates the possibility that future plaintiffs will attempt to distinguish the case on its facts.

Finally, the fact that Simplex was initially regulated as a drug, and that it was reclassified from a Class III to a Class II device since the events at issue in this case, are additional peculiarities that render this case an unsuitable vehicle.

III. THE EIGHTH CIRCUIT CORRECTLY DECIDED THAT A FAILURE-TO-WARN CLAIM CHALLENGING FDA-MANDATED LABELS IS EXPRESSLY PREEMPTED BY THE MDA.

The en banc Eighth Circuit correctly ruled that Brooks' failure-to-warn claim is preempted by the FDA's regulation of the Simplex labeling in question. If Brooks's lawsuit were successful, Minnesota common law would require Howmedica to add "colorful pictographs" (23a n.10) to Simplex's labeling, and to make the other changes proposed by Brooks' expert. The requirements that Brooks seeks to impose constitute state law "requirements" within the meaning of § 360k(a), as a majority of this Court held in *Lohr*, 518 U.S. at 502-04; *id.* at 503-05 (Breyer, J., concurring); *id.* at 509-12 (O'Connor, J., concurring in part and dissenting in part), and reaffirmed in *Geier v. American Honda Motor Co.* 529 U.S. 861, 867 (2000).

It is difficult to imagine a case in which the state tort liability a plaintiff seeks to impose would second-guess to any greater degree a decision made by the FDA. The FDA's control over Simplex's labeling was constant and meticulous. From the time Simplex was initially approved for the United States market throughout the period of Brooks' exposure to the product, the FDA "was deeply involved in drafting and editing [Simplex's warnings]," (27a) and retained approval authority over any safety-related changes (7a-8a).

In *Lohr*, this Court held that the instances of preemption under the MDA would not be "rare." 518 U.S. at 508 (Breyer, J., concurring); *id.* at 509-11 (O'Connor, J., concurring in part and dissenting in part). A case such as this, in which state tort

liability can be imposed only by means of a determination that the FDA was incorrect in its decisions regarding the proper labeling of Simplex, must certainly fall within the range of cases that Congress intended to preempt by including 360k(a) in the MDA. The en banc Eighth Circuit was plainly correct in so ruling.

CONCLUSION

The petition for a writ of certiorari should be denied.

Dated: April 12, 2002

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In The

Supreme Court of the United States

CAROL JEAN BROOKS,

Petitioner,

v.

HOWMEDICA, INC., a Delaware corporation and a division of Pfizer Hospital Products Group; PFIZER, INC.; and HOWMEDICA INTERNATIONAL, LTD.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Eighth Circuit

REPLY BRIEF FOR THE PETITIONER

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REPLY BRIEF FOR THE PETITIONER

Respondents do not contest the importance of the question presented, or the existence of directly conflicting authority among lower federal and state courts. Instead, respondents believe that the split is insufficiently dramatic, and they assert that this case is the wrong vehicle. To a certain extent their response is unresponsive to the petition, see, *e.g.*, Pet. 17-19, 21-22, 27-29 (discussing the Solicitor General's position, *Oja* v. *Howmedica, Inc.*, 111 F.3d 782 (CA10 1997), *Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367 (CA11 1999), and so on), and those arguments will not be repeated. Of lesser importance are respondents' arguments on the merits, which are also substantially met in the petition. A few brief points of rebuttal are, however, appropriate.

1. Specific state requirements. Respondents erroneously suggest that petitioner's suit would result in a specific state requirement because one of her experts proposed specific labeling changes. See Br. in Opp. 12, 24, 28. Even if §360k(a) somehow calls for pre-trial predictions about the character of a hypothetical judgment in petitioner's favor, the preemption argument is not advanced. Minnesota common law does not demand that the finder of fact identify an alternative warning. See Appendix to Respondents' Brief at 6, *Brooks* v. *Howmedica, Inc.*, 236 F.3d 956 (CA8 2001) (No. 00-1188) (reproducing Minnesota's model jury instruction). Petitioner accordingly intends to present alternatives at trial as examples, not for a jury or judge's endorsement. Insofar as such trial presentations nevertheless raise preemption concerns, summary judgment would not be the remedy. Another expert has concluded that respondents' warnings were inadequate

as a matter of state common law, without detailing his preferred labeling. See Appendix to Petitioner's Brief at 461, *Brooks* v. *Howmedica, Inc.*, 236 F.3d 956 (CA8 2001) (No. 00-1188). Regardless, petitioner contends that preemption is foreclosed on a variety of other grounds.

2. Conflict with specific federal requirements. Respondents and petitioner disagree about the standard by which eligible state and federal requirements must be compared. See, *e.g.*, Br. in Opp. 6, 8-10, 14, 19, 22-24, 27. But there should be no dispute about the regulatory record in this case, or the FDA's general policy on warning enhancements. There is no evidence that the FDA considered or opposed enhanced warnings, more detailed warnings, or alternative methods of warning product users about the disease that petitioner contracted: occupational asthma. Accord Pet. 3 (noting petitioner's unrebutted allegation that medical causation was established in 1985). It is true that in the mid-1970s, FDA reviewed (unspecified) evidence within the more general category of inhalation toxicity, and has approved a package-insert warning that refers to respiratory "irritation." Pet. 7, 22. But that is insufficient for preemption. FDA's entry into the general field of respiratory hazards could at most "trigger" preemption "analysis" – it could not end it. *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 507 (1996) (Breyer, J., concurring in part and concurring in judgment); see Pet. 23-26; see also *Goodlin*, 167 F.3d, at 1375 n.14 ("These requests for information [by FDA] may shed light upon the issues the FDA examined but do not impose any specific requirement upon the device.").

In fact, respondents' summary judgment motion was not supported by evidence that FDA has ever

rejected a proposed warning enhancement for the product at issue. See Pet. 8. The record in this case is therefore consistent with the agency's formal policy regarding warning enhancements: they are explicitly permitted, they may be implemented before agency approval, and only after FDA's response might a manufacturer find its warning proposal amended or rejected. See 21 CFR §814.39(d)(2). Considering this and other ways by which FDA can make its views known, there is no sound reason to prematurely preempt by speculating about FDA's position on specifically informing operating-room professionals about disease-specific risks. Cf. 45 Fed. Reg. 67,326, 67,327 cmt. 3, 67,329 cmt. 10 (1980) (pre-*Lohr* FDA preemption ruling concluding that a device-specific state regulation "would interfere with" the agency's own set of device-specific requirements); 42 Fed. Reg. 30,383, 30,384 cmts. 3 & 5 (1977) (noting possibility of preemption for "conflicting" state requirements).*

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* In arguing that the regulatory record in this case is exceptional, respondents are compelled to suggest a distinction between product specifications that "originate" with FDA and those that do not. Br. in Opp. 3; see *id.*, at 27. That proposed line has no basis in law, and it does not undermine the certworthiness of the petition. As the Eleventh Circuit has recognized, such distinctions would *expand* preemption protection as the quality of a manufacturer's application *declines*. Federal law does not create such counterproductive incentives: "an applicant who corrects or modifies a deficient PMA application before receiving the FDA's approval stands in no better position than an applicant whose initial PMA application was flawless." *Goodlin*, 167 F.3d, at 1375. Insofar as the Eighth Circuit held otherwise, it erred and it remains in conflict with the Eleventh Circuit.

Respondents' lack of hesitancy regarding preemption is both a weakness and a central theme of their argument on the merits. They ask the federal judiciary to supply what neither Congress nor the relevant agency has provided: a plain statement of preemption.

3. *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). The argument for delay through percolation is unpersuasive. See Br. in Opp. 15, 20, 24-26; Pet. 13-16, 26-29. Although respondents speculate that anti-preemption rulings will be revised, they fail to provide any actual evidence to suggest that such reconsideration is imminent or likely. See *Webster* v. *Pacesetter, Inc.*, 171 F. Supp. 2d 1, 8-9 (D.D.C. 2001) (following *Goodlin*). In this regard, *Buckman* is useless to lower courts faced with express-preemption defenses. That opinion is overtly limited to boundaries falling far short of this case, see Pet. 28-29, and respondents have not identified any lower federal or state court yet to be confused into mistaking *Buckman* for broader meaning. The regulatory balance at issue there involved FDA's exclusive statutory authority to police fraud against itself, which implicates neither federalism concerns nor preexisting and traditional state duties of manufacturers to their product users. See 531 U.S., at 352. Finally, lower courts do not need *Buckman* to see that the PMA process is "rigorous" – a fact that by itself says nothing about whether FDA has imposed "specific" federal "requirements." *Lohr*, 518 U.S., at 497-501; *id.*, at 506-07 (Breyer, J., concurring in part and concurring in judgment); 21 CFR §808.1(d). A "rigorous" review process is neither necessary nor sufficient to create federal requirements with preemptive force against state tort claims under §360k(a).

For the reasons stated above and in the petition for a writ of certiorari, the petition should be granted.

Respectfully submitted,

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